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Timing of Manufacturer Announcements After Regulatory Authorization of Prescription Digital Therapeutics in the United States: A Retrospective Observational Study

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Abstract

Background

Prescription digital therapeutics are prescription-only software interventions intended to prevent, manage, or treat disease. Regulatory decisions and company announcements are distinct events. This study measured their interval in an identified, potentially incomplete cohort and examined located examples of public disclosure preceding company announcements.

Methods

A retrospective document study used purposive (targeted), nonprobability sampling from a prior candidate list, targeted web searches, and regulatory records to identify prescription therapeutic software delivered through general-purpose mobile, tablet, or web platforms with initial United States Food and Drug Administration (FDA) authorization between January 1, 2017 and October 6, 2026. Hardware-dependent, diagnostic-only, over-the-counter, and unauthorized products were excluded. FDA decision dates were matched to the earliest dated manufacturer-issued authorization announcement located. Calendar-day intervals were summarized using medians, interquartile ranges, means, counts, and percentages. Other dated disclosures were examined separately; the first public posting of FDA documents was not reconstructed.

Results

The identified cohort comprised 15 product families: six De Novo authorizations and nine 510(k) clearances. The median interval was three days (interquartile range, 1.5-6.5; range, 0-180), and the mean was 19.6 days. Three announcements (20.0%) occurred on the decision date, 12 (80.0%) within seven days, and 13 (86.7%) within 30 days. The two longest intervals were 180 and 67 days. Located public-source examples bearing earlier publication dates mentioned authorization before company announcements for four products; historical page versions were not independently reconstructed.

Conclusions

In this identified cohort, most located company announcements followed authorization within one week, with a small number of substantially longer intervals. Regulatory decision dates, manufacturer announcement dates, and evidence of earlier public disclosure should be reported separately. These descriptive findings do not establish the timing of first public availability or explain companies' communication decisions.

Categories: Psychiatry, Public Health, Healthcare Technology

Keywords: digital health, manufacturer announcements, medical devices, prescription digital therapeutics, public disclosure, regulatory authorization, regulatory transparency

Introduction

Prescription digital therapeutics are prescription-only software interventions intended to prevent, manage, or treat disease, distinct from general wellness and diagnostic-only applications. Examples include reSET and Somryst (Pear Therapeutics, Inc., Boston, MA, USA) and EndeavorRx (Akili Interactive Labs, Inc., Boston, MA, USA) [1]. These products have received United States Food and Drug Administration (FDA) authorization for several medical and psychiatric conditions. A previous regulatory study described variation in the labeling of these products, while a broader evidence mapping study examined the literature supporting FDA-authorized digital therapeutics [1,2]. These approaches characterize what products are

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authorized to do and what evidence supports them. The timing of communication about authorization is a separate question.

De Novo authorization classifies novel devices without a legally marketed predicate into class I or II, whereas 510(k) clearance establishes substantial equivalence to a legally marketed predicate [1]. An authorization decision, the appearance of a record in a public database, and a company announcement can occur on different dates. FDA describes weekly additions to its 510(k) database and monthly availability of complete substantially equivalent submission packages [3]. The federal provision addressing release of a 510(k) safety and effectiveness summary assigns a public-availability timeline to FDA; it does not define a manufacturer press release deadline [4]. These processes should therefore not be treated as a single disclosure event.

This distinction matters when reconstructing the development of the field. A news report may use the date of an announcement when describing an authorization, and a later commercial name may differ from the device name in the regulatory record. Without reconciliation, timelines can misclassify the authorization year or exaggerate the interval before information became public. Conversely, a current FDA record does not reveal when a clinician or researcher could first have retrieved it.

In an identified, potentially incomplete cohort of prescription digital therapeutic families, this study measured the calendar-day interval from initial FDA authorization to the earliest located dated company authorization announcement. Secondary objectives were to identify examples of other public disclosures preceding those announcements and to assess whether the available records supported reconstruction of FDA document posting dates. The study addressed observable dates and their interpretation, without attributing motives to manufacturers.

Materials And Methods

Design and scope

This retrospective descriptive study used publicly accessible regulatory records, company communications, and dated public reports retrieved on October 6, 2026. The observation window covered initial authorizations from January 1, 2017 through that date. The calendar boundary defined a contemporary cohort and was not intended to identify the earliest therapeutic software ever authorized. The analysis plan was formalized during retrieval and was not prospectively registered. Product families were selected using purposive (targeted), nonprobability sampling. Candidates were intentionally sought from the earlier labeling study and relevant regulatory and public communication sources, then assessed against the stated eligibility criteria. This approach was not designed to produce population-representative estimates.

The unit of analysis was an initially authorized prescription product family. Eligible products delivered a therapeutic intervention through software on a general-purpose smartphone, tablet, or web platform and had an identifiable FDA De Novo authorization or 510(k) clearance. Products requiring dedicated therapeutic hardware, virtual-reality headsets, physiological sensors, or wearable delivery systems were outside scope. Diagnostic or monitoring applications without a therapeutic indication, nonprescription products, general wellness software, and products available only under enforcement discretion were also excluded. Later modifications, age expansions, and additional authorizations of an included family were not counted as new families. Regulatory authorization, rather than current commercial availability, determined inclusion.

Product identification and source retrieval

The earlier cross-sectional labeling study reviewed public FDA decision summaries, classification orders, and device listings for software-only prescription therapeutics through May 2025; its product list served as candidates rather than as a source of decision dates [1]. Further candidates were sought through indexed FDA pages, subsequent literature, and targeted web searches combining prescription digital therapeutic, FDA, clearance, authorization, product and sponsor names, and the years 2025 and 2026. Searches also used development codes and commercial aliases. Accessible FDA 510(k) and De Novo records were used to confirm individual authorizations [5,6]. A complete downloadable inventory across all relevant product codes was not obtained; the study is therefore an analysis of the identified eligible cohort, not a verified census of all therapeutic software.

For each candidate, searches paired the commercial name, development name, sponsor, or FDA identifier with terms such as "FDA clearance," "authorization," "announcement," and "press release." Manufacturer newsrooms were preferred. Manufacturer-issued releases carried by a press wire, issuer filings, or a clearly attributed syndication were eligible when the original newsroom record was unavailable or less informative. Secondary reporting was used to discover sources and examine alternative public disclosure, but it did not replace an available FDA decision record.

The source hierarchy governed authentication and the role of each source; it did not permit a later newsroom item to displace an earlier qualifying manufacturer-issued communication. Where dates conflicted, the FDA decision record and the event described in any correction letter governed authorization

dating. Manufacturer release text and dated reproductions were compared for announcement dating. Sources without an interpretable day-level date were not assigned a primary endpoint.

FDA product-code descriptions

The formal FDA Product Classification device descriptions were: PWE, computerized behavioral therapy device for substance use disorders; QVO, computerized behavioral therapy device for insomnia; QFT, digital therapeutic software for attention deficit hyperactivity disorder; QMY, computerized behavioral therapy device for treating symptoms; QWI, computerized behavioral therapy device for the treatment of fibromyalgia symptoms; QXC, diabetes digital therapeutic device; SAP, computerized behavioral therapy device for depressive disorders; SCP, computerized behavioral therapy device for anxiety disorders; and SEE, computerized behavioral therapy device for migraine. Product-specific FDA records supplied the code assignments [5,6]. The full FDA regulation description for QMY is computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

Classification labels were checked and distinguished from product-specific indications for use. For example, the FDA database indexed Motivista (CT-155; K254038) under SAP despite its indication concerning negative symptoms of schizophrenia. A classification label was not used to infer an individual product's authorized indication.

Search parameters

Product-specific searches combined commercial and development names, sponsor names, and authorization-announcement terms. These 15 strings were run in Google Search on October 6, 2026, using the English interface and nonpersonalized results. The exact strings, search settings, and aggregate screening outcomes are described in the Appendices.

Date definitions and extraction

The author identified products, assessed eligibility, extracted dates, and verified the selected source records. Dates and source URLs were organized in a spreadsheet-compatible extraction table. No second human reviewer independently checked identification or extraction, so inter-reviewer disagreement resolution was not applicable.

The authorization date was the decision date in the product-specific FDA database record. The decision date referred to the De Novo grant or 510(k) clearance itself; these events were described together as authorizations. Document preparation dates, submission dates, and current website update dates were not substituted for the decision date. A later corrected letter did not reset the original event when it explicitly referred to an earlier decision.

The primary announcement was the earliest dated manufacturer-issued public communication located whose purpose included announcing the applicable authorization. This category included newsroom posts and authorization press releases, including joint developer or commercialization-partner releases. Scientific publications, routine regulatory database entries, and independent media reports were analyzed separately, even when company employees authored a paper. The endpoint is consequently the earliest located announcement under this operational definition; it does not establish that an earlier company communication never existed.

The primary interval equaled the announcement date minus the FDA decision date in calendar days. A same-day announcement was assigned zero. Dates were retained in the calendar date displayed by the source; intraday timing and business-day intervals were not analyzed. For a release with limited date display on its current host, a dated syndication could corroborate the release date. For Somryst (Pear Therapeutics, Inc., Boston, MA, USA), the BioSpace syndication of the manufacturer release explicitly displayed March 26, 2020 [7]. No endpoint was missing among the 15 included families.

Other public disclosures required an explicit statement that authorization had occurred and a day-level publication date. Examples included an FDA news item, a journal article, dated third-party regulatory newsletters, and trade reporting. Their dates demonstrate a dated public mention no later than the identified source, subject to the limitations of retrospective page retrieval; they were not assumed to be the true first public disclosure. Relative social-media dates, search-engine crawl dates, undated pages, and dates inferred from a document filename were not accepted as historical first-publication timestamps. Historic FDA posting dates were left unassigned when the record supplied no verifiable posting event.

This study analyzed publicly available regulatory and organizational documents at the product level. It involved no intervention or interaction with living individuals and no identifiable private information or biospecimens. It therefore did not constitute human-subjects research under 45 CFR 46.102(e), and institutional review board approval and informed consent were not required under the Common Rule for this public-document analysis.

Statistical analysis

Calendar-day intervals and descriptive statistics were calculated using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Product-level intervals and selected summary statistics were cross-checked in a formula-based spreadsheet. Intervals were summarized using the median, interquartile range, mean, minimum, and maximum. Quartiles used linear interpolation between ordered observations, equivalent to the inclusive percentile convention. Counts and percentages were calculated for same-day announcements and announcements within seven, 30, and 60 calendar days, with each threshold including its boundary. Pathway-specific medians were descriptive. An exploratory sensitivity analysis omitted the two longest intervals to show their effect on the distribution. Because the cohort was small, nonrandom, and potentially incomplete, no hypothesis tests, causal models, or population confidence intervals were used.

Results

Cohort and primary intervals

Fifteen identified product families met the operational criteria.

Six (40.0%) entered through De Novo authorization and nine (60.0%) through 510(k) clearance. Table 1 identifies the products, manufacturers, regulatory records, and paired dates; the selected company announcements are cited individually [8-22]. All included decisions occurred at least 60 calendar days before the retrieval date, including the most recent decision on July 30, 2026. This observation does not establish that all newly authorized eligible products were captured.

Product, manufacturer	FDA identifier	Decision date	Announcement date	Days
reSET, Pear Therapeutics, Inc., Boston, MA, USA	DEN160018	2017-09-14	2017-09-14 [8]	0
reSET-O, Pear Therapeutics, Inc., Boston, MA, USA	K173681	2018-12-10	2018-12-10 [9]	0
Somryst, Pear Therapeutics, Inc., Boston, MA, USA	K191716	2020-03-23	2020-03-26 [7,10]	3
EndeavorRx, Akili Interactive Labs, Inc., Boston, MA, USA	DEN200026	2020-06-15	2020-06-15 [11]	0
Parallel, Mahana Therapeutics, Inc., San Francisco, CA, USA	DEN200029	2020-11-25	2020-12-08 [12]	13
Regulora, MetaMe Health, Inc., Chicago, IL, USA	K211463	2021-11-24	2021-11-30 [13]	6
Stanza, Swing Therapeutics, Inc., San Francisco, CA, USA	DEN220083	2023-05-09	2023-05-16 [14]	7
AspyreRx Better Therapeutics, Inc., San Francisco, CA, USA	DEN220058	2023-07-07	2023-07-10 [15]	3
Rejoyn, Otsuka America Pharmaceutical, Inc., Rockville, MD, USA	K231209	2024-03-30	2024-04-01 [16]	2
MamaLift Plus, Curio Digital Therapeutics, Inc., Princeton, NJ, USA	K223515	2024-04-22	2024-04-23 [17]	1
SleepioRx, Big Health, Inc., San Francisco, CA, USA	K233577	2024-08-05	2024-08-08 [18]	3
DaylightRx, Big Health, Inc., San Francisco, CA, USA	K233872	2024-08-30	2024-09-04 [19]	5
CT-132, Click Therapeutics, Inc., New York, NY, USA	DEN240064	2025-04-11	2025-04-15 [20]	4
LumosityRx, Lumos Labs, Inc., San Francisco, CA, USA	K243729	2025-06-13	2025-12-10 [21]	180
Motivista, Click Therapeutics, Inc., New York, NY, USA	K254038	2026-07-30	2026-10-05 [22]	67

TABLE 1: FDA decisions and located manufacturer authorization announcements

Days denotes the calendar-day interval from the FDA decision to the located manufacturer authorization announcement. Dates use YYYY-MM-DD. DEN identifiers indicate De Novo authorization; K identifiers indicate 510(k) clearance. Manufacturer locations are reported for the authorization-era entities. Announcements include joint or partner releases. Selected FDA names differ from commercial names: BT-001 (AspyreRx), Sleepio (SleepioRx), Daylight (DaylightRx), Prismira (LumosityRx), and CT-155 (Motivista). Product-specific FDA records can be retrieved using the identifiers.

The median authorization-to-announcement interval was three days (interquartile range, 1.5-6.5), with a mean of 19.6 days and a range of 0-180 days. Three announcements (20.0%) were dated the same day as the decision, 12 (80.0%) were within seven days, and 13 (86.7%) were within both 30 and 60 days. The medians were 3.5 days for De Novo products and three days for 510(k) products. Table 2 summarizes the distribution.

Measure	Result
Product families, n	15
De Novo/510(k), n	6/9
Median (interquartile range), days	3 (1.5-6.5)
Mean, days	19.6
Minimum-maximum, days	0-180
Same calendar day, n (%)	3 (20.0)
Within 7 days, n (%)	12 (80.0)
Within 30 days, n (%)	13 (86.7)
Within 60 days, n (%)	13 (86.7)
De Novo median, days	3.5
510(k) median, days	3
Excluding two longest intervals, n	13
Median/mean after exclusion, days	3/3.6

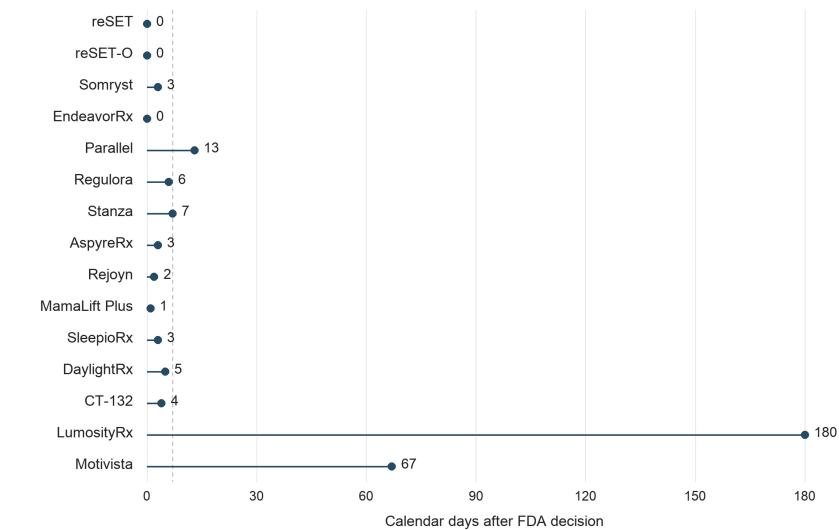
TABLE 2: Distribution of authorization-to-announcement intervals

Thresholds include the stated day. Quartiles use linear interpolation. The exclusion of the two longest intervals is an exploratory sensitivity analysis; both observations remain in the primary cohort.

The longest interval was 180 days for LumosityRx (Lumos Labs, Inc., San Francisco, CA, USA), authorized under the name Prismira, from June 13 to December 10, 2025 [21]. The second longest was 67 days for Motivista (Click Therapeutics, Inc., New York, NY, USA), authorized as CT-155, from July 30 to October 5, 2026 [22]. The other 13 intervals ranged from 0 to 13 days. Omitting the two longest intervals left a median of 3 days and reduced the mean to 3.6 days. Figure 1 displays each product’s interval without converting the company announcement endpoint into an estimate of public silence.

FDA decision to located company announcement

15 product families | Calendar days | Sources retrieved October 6, 2026



Dashed line: 7 days. Announcement timing does not establish first public availability.

FIGURE 1: Calendar days from FDA decision to located company authorization announcement

Each point represents one product family in chronological order of authorization. The horizontal axis is linear and begins at zero; the dashed line marks seven days. The intervals do not measure time to first public availability. FDA: United States Food and Drug Administration. reSET, reSET-O, Somryst, EndeavorRx, Parallel, Regulora, Stanza, AspyreRx, Rejoyn, MamaLift Plus, SleepioRx, DaylightRx, LumosityRx, and Motivista are product names. CT-132 is the development identifier for Click Therapeutics' prescription digital therapeutic for migraine prevention. Regulatory or development aliases are BT-001 (AspyreRx), CT-152 (Rejoyn), Sleepio (SleepioRx), Daylight (DaylightRx), Prismira (LumosityRx), and CT-155 (Motivista). These alternate names refer to the corresponding product families plotted here.

Public disclosures preceding company announcements

Dated public sources preceded the located company announcement for four products (Table 3). A December 1, 2020 report described Parallel's (Mahana Therapeutics, Inc., San Francisco, CA, USA) authorization six days after the November 25 decision and seven days before the December 8 company post. FDA's May 12, 2023 roundup described Stanza's (Swing Therapeutics, Inc., San Francisco, CA, USA) authorization three days after the May 9 decision and four days before the May 16 company post [23].

Product	Dated source	Source date	Days after decision	Days before company notice
Parallel	MedTech Dive: Digital therapeutic De Novos climb with FDA nod to IBS treatment. https://www.medtechdive.com/news/fda-de-novos-mahana-digital-therapeutic-ibs/589813/	2020-12-01	6	7
Stanza	FDA news roundup [23]	2023-05-12	3	4
LumosityRx	Marcus Engineering, LLC: Weekly 510(k) roundup June 16, 2025. LinkedIn newsletter. https://www.linkedin.com/pulse/weekly-510k-roundup-june-16-2025-marcus-engineering-llc-ldmdc	2025-06-16	3	177
LumosityRx	Peer-reviewed article [24]	2025-08-22	70	110
LumosityRx	pharmaphorum: Scoop: Lumos Labs has FDA nod for ADHD DTx Prismira. https://pharmaphorum.com/news/scoop-lumos-labs-has-fda-nod-adhd-dtx-prismira	2025-08-28	76	104
Motivista	Marcus Engineering, LLC: Weekly 510(k) roundup August 03, 2026. LinkedIn newsletter. https://www.linkedin.com/pulse/weekly-510k-roundup-august-03-2026-marcus-engineering-llc-dvawc	2026-08-03	4	63

TABLE 3: Examples of dated public disclosures preceding located company announcements

These sources establish dated mentions preceding the selected announcement. They do not prove the first public-disclosure date. The June 16, 2025 newsletter was the earliest dated non-FDA disclosure identified for Prismira (LumosityRx). The newsletter entries and the journal entry are based on the current text of sources bearing the stated publication dates; historical page versions were not independently reconstructed. The separate trade report provides additional dated corroboration.

For Prismira, the earliest dated non-FDA disclosure identified was Marcus Engineering's June 16, 2025 LinkedIn newsletter, which listed Lumos Labs, Inc., Prismira, and K243729 in its 510(k) roundup, three days after clearance and 177 days before the manufacturer announcement.

The current text of a peer-reviewed article published August 22, 2025 explicitly referred to FDA clearance, providing a dated mention 70 days after the decision and 110 days before the LumosityRx company release [24]. A separate August 28, 2025 trade report described the clearance 76 days after the decision and 104 days before the release. The paper's reference to clearance was used only as evidence of communication; the present study did not evaluate whether the paper's own dataset supported authorization. These sources demonstrate the separation of the two events even without establishing the earliest public posting.

For Motivista (CT-155), Marcus Engineering's August 3, 2026 LinkedIn newsletter listed Click Therapeutics, Inc., Motivista (CT-155), and K254038 in its 510(k) roundup, four days after the July 30 clearance and 63 days before the October 5 manufacturer announcement.

No reliable first-publication date for an FDA database record or decision document was reconstructed for any included product. Consequently, FDA posting intervals were not calculated, and a cohort-wide estimate of the true time to first public disclosure was not reported. Lack of an assigned date represents missing historical information, not an absence of publicly available information.

Reconciliation of regulatory events and names

Parallel's initial event was De Novo authorization DEN200029 on November 25, 2020; the later 510(k) record K211372 was not used as the starting point. EndeavorRx was similarly assigned its initial De Novo event rather than a later prescription expansion. The distinct nonprescription EndeavorOTC product was outside scope. Commercial names also required reconciliation with FDA names, including AspyreRx with BT-001, LumosityRx with Prismira, and Motivista with CT-155.

Document dates provided an additional source of ambiguity. Stanza's May 12, 2023 letter states that it corrects an order originally issued on May 9, 2023; the original date was retained [25]. The currently accessible reSET-O packet also contains a later correction referring to the December 10, 2018 decision, which remained the index event [26]. These examples show why reading the event described by a date is necessary before calculating an interval.

Discussion

Principal findings

In this identified cohort of prescription digital therapeutics, company announcements usually followed FDA authorization within a few days. The median was stable when the two longest intervals were removed, whereas the mean changed substantially. This pattern supports reporting the full distribution and individual dates instead of relying on a mean alone. It does not identify a normative deadline or determine whether a particular interval was appropriate.

Interpretation also depends on the single-author ascertainment and extraction process. A missed earlier eligible manufacturer communication would lengthen an observed interval, whereas an incorrect publication date or an erroneous match between a product alias and an FDA decision could move it in either direction. These possibilities affect the intervals themselves, not only confidence in search completeness, and the mean is especially sensitive to the long intervals. The reported summaries should therefore be interpreted as descriptive estimates for the identified sources and selected cohort, subject to revision after independent human verification. Rechecking the same sources does not replace independent extraction or establish that the earliest historical communication has been found.

The most consequential interpretive finding was that the primary endpoint differed from public disclosure. Parallel, Stanza, LumosityRx, and Motivista had dated public mentions before their located manufacturer announcements. For Prismira (LumosityRx) and Motivista (CT-155), the dated Marcus Engineering newsletters listed the cleared devices three and four days after the respective decisions, whereas the located manufacturer announcements followed at 180 and 67 days (Table 3). These manufacturer-announcement intervals therefore cannot be interpreted as periods during which authorization was unknown or unavailable to the public. Likewise, the absence of a verified earlier source for another product cannot establish that its authorization was undisclosed. A retrospective search observes what remains retrievable and datable.

Comparison with existing literature

The earlier regulatory-label study characterized the authorized uses of prescription digital therapeutics [1]. Amyx et al. identified 436 studies evaluating 45 FDA-authorized digital therapeutics and found that 53.3% had no available results before authorization [2]. Their evidence map selected products with an FDA decision in 2019–2022, whereas the present study examined initially authorized prescription software on general-purpose platforms over 2017–2026. Differences in scope and authorization windows preclude direct denominator comparisons. More fundamentally, their endpoint concerned the availability of clinical evidence, whereas this study measured communications about authorization. The median announcement interval of three days cannot establish whether supporting clinical results were publicly available when a product was announced. Conversely, an extended announcement interval does not establish delayed dissemination of trial results.

Hwang et al. examined 309 cardiovascular, neurologic, and orthopedic devices introduced in the European Union, including 75 classified as major innovations. Pivotal trial results were published for 37 of those 75 devices (49%), with a median interval of 37 months from first regulatory authorization in the United States or European Union to publication [27]. This publication interval measures dissemination of clinical findings and is not a benchmark for the manufacturer-announcement intervals reported here. Their cohort also relied on publicly announced approvals, and the authors acknowledged possible underascertainment of devices introduced without public notice [27]. This parallels the present study's dependence on retrievable communications and reinforces the value of prospective ascertainment from a predefined regulatory inventory.

Clark et al. compared 119 FDA 510(k) summaries with corresponding marketing materials for devices with substantial software components [28]. They classified 15 devices (12.6%) as discrepant and eight (6.7%) as contentious regarding representations of artificial intelligence or machine learning capabilities [28]. Their analysis concerned agreement between commercial claims and regulatory documentation. The present study matched product identity and event dates but did not evaluate therapeutic claims or whether marketing exceeded the authorized indication. A prompt announcement can therefore coexist with incomplete evidence or inaccurate claims, while a later announcement can accurately describe an earlier authorization. None of these possibilities can be resolved from timing alone.

Together, these studies support separate assessment of announcement timing, clinical-evidence availability, trial-publication timing, and fidelity to the regulatory record. A useful product chronology would distinguish authorization, publication of regulatory materials, manufacturer announcement, and publication or posting of clinical results. In this cohort, the decision date and located manufacturer announcement could be dated, while historical FDA posting dates remained unresolved. Communication intervals also do not rank therapeutic benefit, regulatory rigor, or product quality.

Implications for regulatory and clinical communication

Conflating regulatory decisions, manufacturer announcements, and commercial availability can misclassify

both the regulatory milestone and the event experienced by clinicians and patients. Using a press release date as an authorization date shifts the recorded milestone and can distort comparisons of product-development timelines. Treating an authorization or announcement as proof of availability can imply patient access before prescribing, distribution, or reimbursement arrangements have been established. Interpreting the interval as public silence can also support unwarranted conclusions about delayed disclosure or manufacturer conduct. These are potential consequences of date misclassification, not harms demonstrated in this study; the earlier sources for LumosityRx and Motivista illustrate why the distinctions matter.

Reporting separate, source-linked dates makes product histories easier to verify and permits each stakeholder to address a defined question. Regulatory reviewers can verify the decision and device identity; evidence reviewers can align an authorization with the version and clinical evidence evaluated; and access researchers can investigate subsequent prescribing, distribution, and coverage milestones. The benefit is more precise attribution of any observed interval to the transition actually measured. In this study, the interval concerns the earliest located qualifying manufacturer communication. It does not measure FDA review duration, time to market launch, time to reimbursement, or time without any public disclosure.

A practical implication is that authorization timelines should carry an FDA identifier and an explicitly labeled event date. A commercial name alone may fail to connect an announcement with an older regulatory record. Researchers preparing evidence reviews, clinicians investigating a treatment, and journalists reporting a new announcement can reduce ambiguity by recording the decision date separately from the date of the communication. An announcement can accurately report an authorization that occurred earlier; readers need both dates to interpret its timing.

FDA's description of its 510(k) publication process provides context for why the decision record and supporting packet need separate treatment [3]. The public-availability provision for a 510(k) summary is also distinct from a manufacturer's decision to issue a press release [4]. Applying that provision as if it were a company announcement deadline, or extending it without qualification to De Novo documentation, would misclassify the process measured here. A signature date or preparation date within a PDF does not independently establish the date the file became accessible online.

Manufacturers could make announcements easier to verify by stating the FDA decision date, identifying the clearance or De Novo number, linking to the product-specific regulatory record, and naming any development-to-commercial alias. These are proposed communication practices, not findings that each included announcement lacked these elements. FDA records could also distinguish the original decision date, first public posting, and later replacement or correction dates. Such fields would make future studies less dependent on historical web reconstruction.

Several possible processes could separate authorization from a company announcement, including decisions about commercial readiness or coordination of communications. These possibilities were not measured and should not be assigned to individual products. The study did not obtain internal company records, interview manufacturers, or investigate legal disclosure obligations. It therefore cannot infer intent, concealment, noncompliance, investor effects, or delayed patient access from the observed intervals.

Future research

Future research should construct a broader cohort from a predefined FDA inventory and prospectively specify product-family rules, source hierarchy, exact search strategies, and handling of aliases, updated pages, and missing dates. Dated query logs, record-level screening decisions, and archived document copies should be retained, with independent human extraction and adjudication of disagreements. Separate endpoints should capture the FDA decision, first verified public posting of regulatory records, manufacturer announcement, first located nonmanufacturer disclosure, first documented prescribing or distribution availability, and coverage. With a larger cohort and verified endpoints, analyses could examine variation by pathway, indication, and calendar period and test whether communication intervals are associated with actual access delays. Such work would distinguish observable associations from operational or commercial explanations that were not measured here.

Strengths and limitations

The study matched each included authorization to an FDA identifier and retained paired source URLs, aliases, and an explicit definition of the announcement event. Calendar-day calculations are reproducible, and alternative public disclosures are presented without replacing the primary endpoint. Corrected letters and later authorizations were reconciled with the original event rather than treated as new starting dates.

Several limitations constrain interpretation. First, cohort ascertainment combined a prior candidate list with targeted and indexed searches. It was not an exhaustive export of the FDA device inventory, and relevant products may have been missed. The restriction to general-purpose software and the 2017 start date further limit generalizability. Products that never generated an easily discoverable announcement may be especially difficult to identify, potentially shortening the observed distribution. Product identification and date

extraction were performed in a single-author workflow without an independent second human reviewer, creating potential selection and extraction error.

Second, the earliest located announcement is a search-dependent endpoint subject to web-content survivorship bias. Deleted pages, migrated newsrooms, incomplete indexing, inaccessible materials, and communications outside the searched channels may conceal earlier announcements. Syndications can preserve a release date but may also carry update dates. The analysis used the identified release date and documented the selected source, without claiming to have reconstructed every original page version.

Third, historical FDA posting dates were unavailable. Current database and document access cannot establish past availability, while an isolated dated report supplies evidence of a public mention rather than a comprehensive disclosure history. The secondary findings are therefore illustrative and should not be interpreted as the sensitivity or completeness of an all-channel surveillance system.

Fourth, the small number of heterogeneous products does not support comparisons between sponsors or causal interpretation of pathway differences. The exploratory removal of the two longest intervals describes the influence of those observations; it is not a basis for discarding them from the primary findings.

Finally, author relationships with companies in this field require transparent disclosure and cautious interpretation. The study evaluates publicly available data and retains unfavorable as well as favorable observations without making company-level judgments. Independent replication with archived source versions, prospective recording of FDA publication events, and a complete predefined device inventory would strengthen the evidence.

Conclusions

Among 15 identified product families, the typical interval from FDA authorization to a located company announcement was short, although two products had substantially longer intervals. Earlier dated public disclosures showed that company announcement timing cannot be equated with the duration of information unavailability. Future timelines should identify the regulatory event, company announcement, and evidence of public posting separately, with source links and explicit treatment of missing historical dates.

Appendices

Search protocol

The study used purposive (targeted), nonprobability sampling of initially authorized prescription product families, with an FDA decision from January 1, 2017 through October 6, 2026. The product-family definition, inclusion and exclusion criteria, source hierarchy, and manufacturer-announcement endpoint are specified in Materials and Methods. The product-specific Google searches examined manufacturer announcements for the 15 included product families; they were not an exhaustive inventory of all eligible devices.

The selected primary-source inventory contains 31 source entries: 15 FDA records, 15 selected manufacturer notices, and one additional Somryst date-corroboration source. These are selected sources, not a screening denominator. Three documented exclusion examples are Parallel K211372 (June 2, 2021; later authorization of an included family), EndeavorRx K231337 (December 13, 2023; later prescription expansion), and EndeavorOTC K233496 (June 14, 2024; nonprescription product). These examples are not represented as a complete historical exclusion count.

Exact Google Queries and Execution Settings

The following product-specific strings combined product names, aliases, sponsors, and authorization-announcement terms in Google Search. The English interface was used (hl=en) with the recorded nonpersonalized-results choice (peek_pws=0). No date restriction was entered in Google.

Q01 - reSET: "reSET" "Pear Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

Q02 - reSET-O: ("reSET-O" OR "reSET O") (Pear OR Sandoz) (FDA OR clearance OR authorization) (announcement OR "press release")

Q03 - Somryst: "Somryst" "Pear Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

Q04 - EndeavorRx: ("EndeavorRx" OR "AKL-T01" OR Endeavor) Akili (FDA OR clearance OR authorization) (announcement OR "press release")

Q05 - Parallel: ("Parallel" OR "Mahana IBS") "Mahana" (FDA OR clearance OR authorization) (announcement

OR "press release")

Q06 - Regulora: "Regulora" "MetaMe" (FDA OR clearance OR authorization) (announcement OR "press release")

Q07 - Stanza: "Stanza" "Swing Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

Q08 - AspyreRx: ("AspyreRx" OR "BT-001" OR BT001) "Better Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

Q09 - Rejoyn: ("Rejoyn" OR "CT-152" OR CT152) (Otsuka OR Click) (FDA OR clearance OR authorization) (announcement OR "press release")

Q10 - MamaLift Plus: "MamaLift Plus" Curio (FDA OR clearance OR authorization) (announcement OR "press release")

Q11 - SleepioRx: ("SleepioRx" OR Sleepio) "Big Health" (FDA OR clearance OR authorization) (announcement OR "press release")

Q12 - DaylightRx: ("DaylightRx" OR Daylight) "Big Health" (FDA OR clearance OR authorization) (announcement OR "press release")

Q13 - CT-132: ("CT-132" OR CT132) "Click Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

Q14 - LumosityRx / Prismira: ("LumosityRx" OR "Lumosity Rx" OR Prismira) (Lumos OR Lumosity) (FDA OR clearance OR authorization) (announcement OR "press release")

Q15 - Motivista / CT-155: ("Motivista" OR "CT-155" OR CT155) "Click Therapeutics" (FDA OR clearance OR authorization) (announcement OR "press release")

FDA Databases and Exact Lookup Parameters

FDA 510(k) Premarket Notification and De Novo databases were used for product-specific decision records; the FDA Product Classification database supplied formal device descriptions. The 510(k) product-code searches used the URL pattern https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?start_search=1&productcode=CODE, with CODE entered separately as PWE, QVO, QFT, QMY, QWI, QXC, SAP, SCP, or SEE. A complete export across these codes was not obtained. A product-code query alone was not treated as proof of initial authorization, prescription status, or eligibility.

Individual 510(k) records use <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=IDENTIFIER>. Individual De Novo records use <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=IDENTIFIER>. The exact identifier and code pairs are: reSET, DEN160018/PWE; reSET-O, K173681/PWE; Somryst, K191716/QVO; EndeavorRx, DEN200026/QFT; Parallel, DEN200029/QMY; Regulora, K211463/QMY; Stanza, DEN220083/QWI; AspyreRx (BT-001), DEN220058/QXC; Rejoyn, K231209/SAP; MamaLift Plus, K223515/SAP; SleepioRx (Sleepio), K233577/QVO; DaylightRx (Daylight), K233872/SCP; CT-132, DEN240064/SEE; LumosityRx (Prismira), K243729/QFT; and Motivista (CT-155), K254038/SAP.

FDA classification-record lookups use https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?productcode=CODE&start_search=1, with each of the nine codes above entered separately. The nine descriptions and all 15 decision-date/code mappings were checked on October 6, 2026 against the current FDA records. The database classification label and the individual indication for use were recorded separately; SAP is the current database assignment for Motivista and is not a substitute for its product-specific indication.

Source Selection and Screening Outcomes

FDA decision records governed authorization dates, with corrected letters read to distinguish an original decision from a later correction. Manufacturer newsrooms were preferred for announcement authentication; manufacturer-issued press-wire releases, issuer filings, joint or partner releases, and clearly attributed syndications were also eligible. Source hierarchy did not allow a later newsroom post to replace an earlier qualifying manufacturer communication. A notice had to explicitly announce the applicable initial authorization and carry an interpretable calendar date. Earlier eligible notices were sought; same-date notices were retained as confirmation. A dated secondary report or scientific publication could support the

separate public-disclosure analysis but did not qualify as a manufacturer authorization announcement.

The 15 Google queries returned 135 organic result occurrences (nine per query), all of which were screened. There were 129 distinct normalized URLs after six repeated URL occurrences and 125 document groups after grouping four verified cross-URL release mirrors. At the result-occurrence level, 17 were dated manufacturer notices confirming a selected announcement date, 114 were excluded from the earlier-notice endpoint, and four manufacturer LinkedIn posts remained unresolved because an exact publication date could not be verified. Exclusion reasons were non-manufacturer secondary reporting (58), later than the selected notice (24), a different product or regulatory event (11), an undated index or profile (9), a different product (5), a regulatory source rather than a manufacturer notice (5), a nontarget notice (1), and a date after the eligibility cutoff (1).

The four unresolved records concerned Rejoyn, MamaLift Plus, CT-132, and Motivista. Three retrieved posts displayed relative ages only; the MamaLift Plus post could not be retrieved. No exact dates were inferred from relative labels, URL identifiers, or linked releases. Full retrieval was attempted for 26 distinct Google-result URLs; 25 were retrieved and one was not. Direct checks of 16 selected-source URLs supported all 15 selected manufacturer-notice dates, including dated syndication corroboration for Somryst. An additional retrieval of the BioSpace syndication cited in reference 7 also confirmed the Somryst date, bringing the combined direct-source checks to 17 successfully retrieved URLs. These direct checks are not added to the Google screening denominator.

No earlier dated qualifying manufacturer notice was confirmed among the screened records. The selected reSET and Regulora announcements did not appear among the first-page Google results screened on October 6, 2026. Direct access to those source pages confirmed the announcement dates used in the analysis. These observations demonstrate the limits of a bounded search. Zero confirmed earlier notices is not evidence that no earlier notice exists.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Shaheen E. Lakhan

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References

1. Lakhan SE: Decoding FDA labeling of prescription digital therapeutics: a cross-sectional regulatory study . Cureus. 2025, 17:e84468. [10.7759/cureus.84468](https://doi.org/10.7759/cureus.84468)
2. Amyx M, Alebouyeh F, Phi NT, Ravaud P, Tran VT: Mapping the evidence supporting FDA-authorized digital therapeutics, before and after authorization. NPJ Digit Med. 2026, 9:[10.1038/s41746-026-02737-9](https://doi.org/10.1038/s41746-026-02737-9)

3. 510(k) submission process . Accessed: October 6, 2026: <https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process>.
4. 21 CFR 807.95. Confidentiality of information . Accessed: October 6, 2026: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E/section-807.95>.
5. 510(k) premarket notification database . Accessed: October 6, 2026: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.
6. Device classification under section 513(f)(2)(De Novo) . Accessed: October 6, 2026: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm>.
7. Pear Therapeutics obtains FDA authorization for Somryst, a prescription digital therapeutic for the treatment of adults with chronic insomnia (BioSpace syndication). (2020). Accessed: October 6, 2026: <https://www.biospace.com/pear-therapeutics-obtains-fda-authorization-for-somryst-a-prescription-digital-therapeutic-f...>
8. Pear Therapeutics obtains FDA clearance of the first prescription digital therapeutic to treat disease . (2017). Accessed: October 6, 2026: <https://www.prnewswire.com/news-releases/pear-therapeutics-obtains-fda-clearance-of-the-first-prescription-digital-th...>
9. Sandoz Inc. and Pear Therapeutics obtain FDA clearance for reSET-O to treat opioid use disorder . (2018). Accessed: October 6, 2026: <https://www.novartis.com/news/media-releases/sandoz-inc-and-pear-therapeutics-obtain-fda-clearance-reset-otm-treat-op...>
10. Pear Therapeutics obtains FDA authorization for Somryst, a prescription digital therapeutic for the treatment of adults with chronic insomnia. (2020). Accessed: October 6, 2026: <https://www.businesswire.com/news/home/20200326005278/en/Pear-Therapeutics-Obtains-FDA-Authorization-for-SOMRYST-a-Pr...>
11. Akili announces FDA clearance of EndeavorRx for children with ADHD, the first prescription treatment delivered through a video game. (2020). Accessed: October 6, 2026: <https://www.akiliinteractive.com/news-collection/akili-announces-endeavortm-attention-treatment-is-now-available-for-...>
12. Mahana Therapeutics obtains FDA marketing authorization for the first prescription digital therapeutic to treat irritable bowel syndrome. (2020). Accessed: October 6, 2026: <https://medium.com/mahana-therapeutics/mahana-therapeutics-obtains-fda-marketing-authorization-for-the-first-prescrip...>
13. MetaMe Health receives FDA clearance for Regulora, the first FDA-authorized treatment specifically for abdominal pain due to irritable bowel syndrome (IBS). (2021). Accessed: October 6, 2026: <https://www.prweb.com/releases/metame-health-receives-fda-clearance-for-regulora-r-the-first-fda-authorized-treatment...>
14. FDA authorizes Stanza to treat fibromyalgia symptoms. (2023). Accessed: October 6, 2026: <https://swingtherapeutics.com/swing-therapeutics-fda-stanza-to-treat-fibromyalgia-symptoms/>.
15. Better Therapeutics receives FDA authorization for AspyreRx to treat adults with type 2 diabetes . (2023). Accessed: October 6, 2026: https://www.sec.gov/Archives/edgar/data/1832415/000095017023032690/bttx-ex99_1.htm.
16. Otsuka and Click Therapeutics announce the U.S. Food and Drug Administration (FDA) clearance of Rejoyn, the first prescription digital therapeutic authorized for the adjunctive treatment of major depressive disorder (MDD) symptoms. (2024). Accessed: October 6, 2026: <https://www.otsuka-us.com/news/rejoyn-fda-authorized>.
17. Curio Digital Therapeutics Inc. announces the U.S. Food and Drug Administration (FDA) clearance of MamaLift Plus, the first prescription digital therapeutic authorized for the treatment of postpartum depression (PPD). (2024). Accessed: October 6, 2026: <https://www.biospace.com/curio-digital-therapeutics-inc-announces-the-u-s-food-and-drug-administration-fda-clearance-....>
18. US FDA grants clearance for SleepioRx. (2024). Accessed: October 6, 2026: <https://www.bighealth.com/news/us-fda-grants-clearance-for-sleepiorx>.
19. US FDA grants clearance for DaylightRx. (2024). Accessed: October 6, 2026: <https://www.bighealth.com/news/us-fda-grants-clearance-for-daylightrx>.
20. Click Therapeutics announces FDA marketing authorization for CT-132, the first prescription digital therapeutic for the preventive treatment of episodic migraine in the United States. (2025). Accessed: October 6, 2026: <https://www.clicktherapeutics.com/news/click-therapeutics-announces-fda-marketing-authorization-for-ct-132-the-first-....>
21. Lumosity announces FDA clearance of LumosityRx, a prescription digital therapeutic for adults with ADHD . (2025). Accessed: October 6, 2026: <https://www.lumosity.com/en/press/lumosity-rx-fda-clearance/>.
22. FDA clears Motivista (CT-155), the first authorized treatment for negative schizophrenia symptoms. (2026). Accessed: October 6, 2026: <https://www.clicktherapeutics.com/news/fda-clears-motivista-ct-155-the-first-therapeutic-indicated-for-the-treatment-....>
23. FDA Roundup: May 12, 2023. (2023). Accessed: October 6, 2026: <https://www.fda.gov/news-events/press-announcements/fda-roundup-may-12-2023>.
24. Osman AM, Madore KP, Jaffe PI, Offidani E, Childress AC, Newcorn JH, Schafer RJ: Real-world effectiveness of a widely available digital health program in adults reporting a lifetime diagnosis of ADHD. *Npj Ment Health Res.* 2025, 4:38. [10.1038/s44184-025-00157-3](https://doi.org/10.1038/s44184-025-00157-3)
25. Stanza, DEN220083. Corrected De Novo order dated May 12, 2023, referring to the original May 9, 2023 order. (2023). Accessed: October 6, 2026: https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220083.pdf.
26. reSET-O, K173681. Corrected clearance correspondence dated May 23, 2019 referring to the December 10, 2018 decision. (2019). Accessed: October 6, 2026: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173681.pdf.
27. Hwang TJ, Sokolov E, Franklin JM, Kesselheim AS: Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study. *BMJ.* 2016, 353:i3323. [10.1136/bmj.i3323](https://doi.org/10.1136/bmj.i3323)
28. Clark P, Kim J, Aphinyanaphongs Y: Marketing and US Food and Drug Administration clearance of artificial intelligence and machine learning enabled software in and as medical devices: a systematic review. *JAMA Netw Open.* 2023, 6:e2321792. [10.1001/jamanetworkopen.2023.21792](https://doi.org/10.1001/jamanetworkopen.2023.21792)