July 30, 2026

Click Therapeutics, Inc.
Austin Speier
Chief Strategy Officer
80 White St.
3rd Floor
New York, New York 10013

Re: K254038
Trade/Device Name: Motivista (CT-155)
Regulation Number: 21 CFR 882.5801
Regulation Name: Computerized behavioral therapy device for psychiatric disorders
Regulatory Class: Class II
Product Code: SAP
Dated: June 30, 2026
Received: June 30, 2026

Dear Mr. Speier:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAMELA D. SCOTT -S

Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254038

Device Name
Motivista (CT-155)

Indications for Use *(Describe)*
Motivista (CT-155) is a prescription digital therapeutic indicated for the treatment of negative symptoms of schizophrenia as an adjunct to clinician-managed outpatient care, including antipsychotic therapy, in patients 18 years of age and older with clinically stable positive symptoms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

1. Sponsor Information

1.1. Applicant

Company Name: Click Therapeutics, Inc.
Address: 80 White St, 3rd Floor, New York, NY, 10013
Telephone: 332-244-0108
Contact Name: Austin C. Speier
Chief Strategy Officer
austin@clicktherapeutics.com

2. Device Information

2.1. Proposed Device

Device Name: CT-155
Trade Name: Motivista
Device Type: Prescription Digital Therapeutic
Device Classification: 21 CFR 882.5801, Computerized Behavioral Therapy Device for Psychiatric Disorders
Regulatory Class: Class II
Product Code: To Be Determined

2.2. Predicate Device

Device Name: CT-152
Trade Name: Rejoyn
Device Type: Prescription Digital Therapeutic
Device Manufacturer: Otsuka America Pharmaceutical, Inc.
Premarket Notification Number: K231209
Device Classification: 21 CFR 882.5801, Computerized Behavioral Therapy Device for Psychiatric Disorders
Regulatory Class: Class II
Product Code: SAP

2.3. Device Description

Motivista is a mobile app that delivers a 16-week, software-based therapeutic intervention. The app employs evidence-based cognitive and behavioral treatment components such as behavioral activation, cognitive restructuring, social skills training, positive affect training, and distress tolerance skills, alongside other digital interventions, approaches, and treatment techniques such as Adaptive Goal Setting and establishing a Digital Working Alliance process. Motivista's journey is systematically structured to guide the patient towards a meaningful improvement in negative symptoms of schizophrenia. Therapeutic content is grouped into three phases: Orientation Phase (21 days in length), Goal Attainment Phase (84 days in length) and

Consolidation Phase (7 days in length). Treatment is delivered through lessons, goals, activities, tools, daily check-ins, and personalized messaging.

3. Intended Use and Indications for Use

3.1. Intended Use

Motivista is a prescription digital therapeutic intended to be used for the treatment of negative symptoms of schizophrenia as an adjunct to clinician-managed outpatient care.

3.2. Indications for Use

Motivista is a prescription digital therapeutic indicated for the treatment of negative symptoms of schizophrenia as an adjunct to clinician-managed outpatient care, including antipsychotic therapy, in patients 18 years of age and older with clinically stable positive symptoms.

3.3. Comparison to Predicate

Motivista and its predicate, Rejoyn, are both intended for use as computerized behavioral therapy devices for psychiatric disorders, as classified under 21 CFR 882.5801. The Indications for Use statement for Motivista is not identical to the predicate device and differs for the primary psychiatric diagnosis of the studied patient populations and for whom the device is intended: schizophrenia (Motivista) and Major Depressive Disorder (MDD) (Rejoyn).

Demonstration of substantial equivalence is supported by Motivista's pivotal clinical study (CONVOKE; CT-155-R-001) results, which supported the safety and effectiveness of Motivista, and compliance with applicable special controls, consistent with the predicate device. The substantial equivalence determination was supported by pediatric extrapolation data. This supportive data was needed due to the limited enrollment of patients aged 18–21 years in Motivista's pivotal clinical study.

4. Comparison of Technological Characteristics

Motivista and Rejoyn have similar technological characteristics (provided in Table 1). Both devices employ digital delivery mechanisms for behavioral therapy via a smartphone application and feature therapeutic content designed to address psychiatric disorders. Variations in content delivery and treatment duration between Motivista and Rejoyn are due to the different intended patient populations specific to Motivista and Rejoyn. The variations in content and duration between Motivista and Rejoyn does not raise new questions of safety and effectiveness.

Table 1. Substantial Equivalence Table Comparing Motivista to Rejoyn (Predicate)

Property or Characteristic	**Subject Device: Motivista**	**Predicate Device: Rejoyn (K231209)**[1]
Access	Rx Only	Rx Only
Where used	Home use	Home use
Adjunctive Application	Yes - adjunctive to standard of care (SOC)	Yes - adjunct to treatment as usual (TAU)
Target Conditions	Psychiatric Condition - Schizophrenia	Psychiatric Condition - MDD
Device Type	Software as a Medical Device (SaMD) mobile application	Software as a Medical Device (SaMD) mobile application
Mechanism of Action	Computerized Behavioral Therapy	Computerized Behavioral Therapy
Mobile Platform	Smartphones (iOS and Android)	Smartphones (iOS and Android)
Technology	Digital therapeutic treatment sessions (44 lessons and 17 goals)) over a 16-week period, grouped into 8 modules in 3 phases (orientation, goal attainment, consolidation) of treatment.	Digital therapeutic treatment sessions (18 EFMT exercises and 18 brief, CBT-based lessons) over a 6-week period, followed by a 4-week extension period.
Validated Form of Behavioral Therapy	Motivista employs evidence-based cognitive and behavioral interventions.	A combination of Emotional Faces Memory Task (EFMT) and Cognitive Behavioral Therapy (CBT) based lessons.
Labeling	Patient and provider labeling	Patient and provider labeling

5. Performance Testing

5.1. Summary of Non-clinical Performance Testing

Special controls for device types within computerized behavioral therapy device for psychiatric disorders require that the software must be described in detail in the software requirements specification (SRS) and the software design specification (SDS). Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.

The software and cybersecurity documentation provided in the 510(k) is consistent with the FDA Guidance documents entitled *Content of Premarket Submissions for Device Software*

[1] Rejoyn 510(k) Summary: https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231209.pdf

Functions, issued June 2023; *Off-the-Shelf Software Use in Medical Devices,* issued August 2023; and *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions,* issued June 2025.

Software verification and validation testing was completed, and software documentation was provided in the 510(k) as recommended by the 2023 FDA guidance. Cybersecurity testing was completed in accordance with the 2025 FDA guidance. Software documentation demonstrates that Motivista effectively implements the behavioral therapy model.

5.2. Summary of Clinical Performance Testing

The indications for use for Motivista are supported by the results of a multi-center, randomized, double-blind (patients also blinded to hypothesis), digital-controlled clinical study (CT-155-R-001, also referred to as “CONVOKE”). CONVOKE demonstrated that treatment with Motivista reduced negative symptoms of schizophrenia as evaluated by the Clinical Assessment Interview for Negative Symptoms, Motivation and Pleasure (CAINS-MAP) scale, without any device-related serious adverse events.

5.2.1. Study Population

The CONVOKE pivotal clinical study enrolled participants (18 years or older) with at least a 6 month history of diagnosed schizophrenia per the Diagnostics and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), and who experienced moderate to severe negative symptoms. Participants were eligible if they had been on a stable dose of antipsychotic medication(s) for 12 weeks prior to randomization, were in the stable phase of illness (as assessed by the investigator after review of medical records or documented discussion with the treating healthcare provider, or from determination of the Principal Investigator), had stable housing for 12 weeks prior to screening, had outpatient treatment status at the time of screening and no inpatient treatment for schizophrenia within 12 weeks prior to screening, and had obtained an average score of ≥2 (moderate to severe) in at least two of the three CAINS-MAP domains (Social, Work or Recreational) at the Screening Visit and at baseline (Day 1).

Key exclusion criteria included (1) treatment with more than two antipsychotic medications, (2) prominent positive symptoms as indicated on the PANSS scale, (3) psychotherapy (current or within 13 weeks prior to screening), (4) DSM-5 diagnosis for schizophreniform, schizoaffective, psychosis non-specific disorders, current episode of depression/mania/hypomania, (5) moderate to severe substance use disorder (except tobacco; within 12 months prior to screening), and (6) active suicidal ideation with method or intent within the last 3 months or suicidal behavior within the last 6 months (as assessed by the C-SSRS) or presentation with suicide risk (based on opinion of the investigator).

5.2.2. Study Design

Participants took part in the study for up to 22 weeks, including a two-week Screening Period, 16-week intervention period, and up to four-week Follow-Up period (see Figure 1).

After verification of preliminary eligibility in the Screening Period, participants were enrolled and granted access to a mobile application (the “Study App”). At baseline, participants were reassessed for eligibility and, if confirmed, were randomized in a 1:1 ratio to receive either the Motivista intervention or a Digital Control. The Digital Control was designed as a comparable digital experience to match Motivista with similar daily participant engagement and frequency of app use.

During the intervention period, all randomized participants were expected to use the Study App daily. Participants in both arms also received messages prompting participants to maintain engagement with the Study App. Each day, participants were expected to complete at least one task in the Study App, and adherence was monitored.

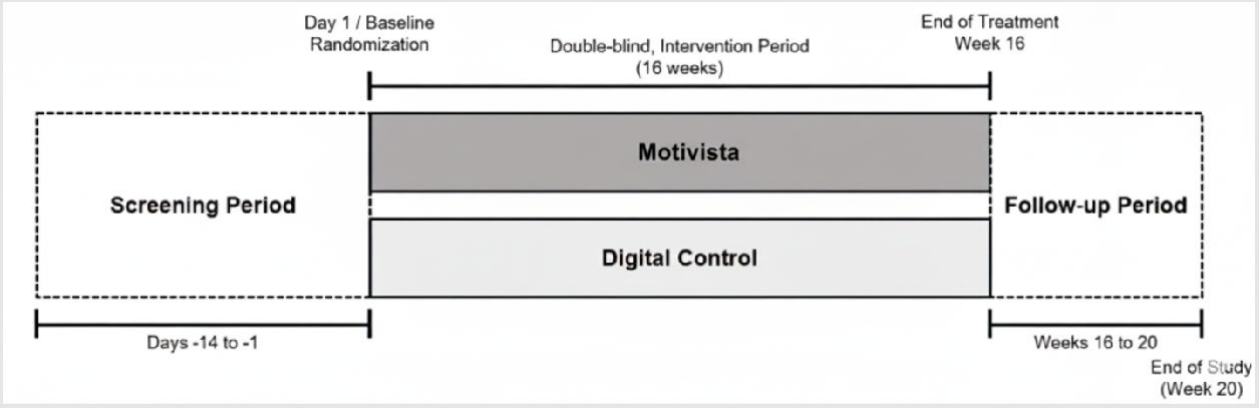

Figure 1. Study Design Schema for the Motivista’s Pivotal Clinical Study

5.2.3. Outcome Measures

The primary objective of the pivotal clinical study was to evaluate the effectiveness and safety of Motivista in reducing negative symptoms in participants diagnosed with schizophrenia. The primary effectiveness endpoint was the change from baseline to Week 16 in experiential negative symptoms, as assessed by Clinical Assessment Interview for Negative Symptoms, Motivation and Pleasure Scale (CAINS-MAP), as compared with Digital Control. Other clinical outcomes were evaluated as secondary endpoints at Weeks 8 and 16, such as change in motivation and pleasure symptoms at Week 8 as assessed by CAINS-MAP, change in expressive negative symptoms as assessed by Clinical Assessment Interview for Negative Symptoms, Expressivity Scale (CAINS-EXP), change in Positive and Negative Syndrome Scale (PANSS) total score, change in PANSS positive subscale, change in social functioning as assessed by Personal and Social Performance Scale (PSP), change in self-reported defeatist beliefs as assessed by the Defeatist Beliefs Subscale of the Dysfunctional Attitudes Scale

(DAS), Patient Global Impression of Improvement Scale (PGI-I), and Patient Global Impression of Severity (PGI-S).

Motivista has not been studied for treating the positive symptoms of schizophrenia and is not intended for that use.

The primary effectiveness endpoint was evaluated using Mixed Model Repeated Measures (MMRM) on the Intent-to-Treat (ITT) analysis set, which included all unique participants randomized, based on observed data and was tested at a significance level of 0.05. All other effectiveness endpoints were tested at a nominal 0.05 level (2 sided) without adjusting for multiplicity.

5.2.4. Participant Disposition

Table 2 summarizes the various analysis sets used in the CONVOKE pivotal clinical study. In the CONVOKE pivotal clinical study, of the 1,205 individuals screened for participation, 457 unique participants were randomized: 227 to the Motivista arm and 230 to the Digital Control arm (ITT Set). The ITT Set was the primary population used for the effectiveness analyses. Participant demographics between the two arms were fairly balanced and were reflective of the intended patient population within the US. 62.6% of participants were male in the Motivista arm with 58.7% male in the Digital Control. The mean age at baseline was 45.8 (±12.46) years; 46.2 (±12.44) years in the Motivista arm and 45.3 (±12.50) years in the Digital Control arm. The population was mostly Black or African American (53.4%) and White or Caucasian (39.6%) and was balanced across arms. Annual income was <$25,000 per year in 63.5% of participants and 80.3% of participants were unemployed. At baseline, the majority of participants had a length of time since diagnosis of schizophrenia greater than 5 years (83.2%) and were taking only one antipsychotic medication (88%); of antipsychotic medication prescribed, most were second-generation antipsychotics (91.5%).

Supportive effectiveness analyses were also performed on the modified ITT (mITT) Set and the Per Protocol (PP) Set, as described in Table 2 below. Safety analyses were performed on the Safety Analysis Set, which included all participants who were exposed to Motivista or the Digital Control (i.e., completed at least one available daily activity in the Study App during the intervention period). In the CONVOKE pivotal clinical study, the Safety Set consisted of 459 participants (n = 228 for Motivista arm; n = 231 for Digital Control arm).

Table 2. CONVOKE Study Analysis Sets

Analysis Set	Description	Motivista	Digital Control	Total
Intent-toTreat (ITT)	All unique randomized participants	227	230	457
Modified Intent-to-Treat (mITT)	All unique randomized participants who completed at least one available daily activity in the Study App and have at least one post-baseline CAINS assessment	201	204	405
Per Protocol (PP)	All unique randomized participants who completed the treatment and at least one available daily activity in the Study App on at least 67 days during the intervention period without a major protocol deviation impacting the primary endpoint	119	152	271
Safety Set	All randomized participants completed at least one available daily activity in the Study App	228	231	459

5.2.5. Safety

Adverse events were reported by participants through communications with the research team and assessed for relatedness to Motivista by the investigator.

The overall rate of treatment-emergent adverse events (TEAEs) was 7.9% in the Motivista arm and 11.7% in the Digital Control arm. Psychiatric disorders were reported as TEAEs in 2.0% of participants (three in the Motivista arm and six in the Digital Control arm). Of all the TEAEs, two reported psychotic disorders were considered to be related to study intervention: one participant in the Motivista arm (who experienced two instances of “psychotic disorder”, but neither led to study discontinuation) and one participant in the Digital Control arm (who experienced "irritability" that led to study discontinuation). None of the TEAEs considered as related to the study intervention were serious TEAEs. No TEAEs led to participant discontinuation in the Motivista arm, and two TEAEs led to participant discontinuation in the Digital Control arm.

Additionally, there were two TEAEs reported as a serious for worsening “schizophrenia” in the Digital Control, but both were assessed as not related to the study intervention and none of this type in the Motivista arm. No participants died during the course of the study.

In the pivotal clinical study (Motivista N=228, Digital Control N=231), C-SSRS lifetime history of suicidal ideation or behavior at baseline was similar between arms (25.6% Motivista vs. 24.1%

Digital Control). During the post-baseline period (Weeks 4–16), suicidal ideation or behavior was reported by 7 unique participants (10 ideation, 2 behavior reports) in the Motivista arm and 4 unique participants (4 ideation, 1 behavior report) in the Digital Control arm, with per-visit incidence of any suicidal ideation or behavior ranging from 1.1%–1.5% and 0.5%–0.9%, respectively (range depending on whether the visit was at week 4, 8, 12, 16 and the reportable safety set at each visit time point).

In the pivotal clinical study, "psychotic disorder" referred to transient exacerbations of schizophrenia, reported twice as non-serious adverse events by a single 37-year-old male on risperidone (Event 1: moderate, resolved in 2 days post-ER visit; Event 2: mild, resolved in 1 day in an outpatient setting). Both episodes were managed with temporary outpatient risperidone dose adjustments (3 mg to 4 mg daily) without requiring changes or discontinuation of Motivista. The investigator and medical monitor assessed the events as "possibly related" solely due to temporal concurrence with Motivista usage, whereas the sponsor assessed them as "not related" and reflective of normal disease fluctuation. Because the events were non-serious, brief, and quickly resolved, the overall risk-benefit profile supported maintaining treatment throughout both episodes.

5.2.6. Effectiveness

Data from CONVOKE indicates that Motivista provides a benefit in reducing negative symptoms to participants with negative symptoms of schizophrenia as an adjunct to standard of care for patients. CONVOKE’s primary effectiveness endpoint was the change in experiential negative symptoms from baseline to Week 16 as assessed by CAINS-MAP. CAINS-MAP is a nine-item Motivation and Pleasure subscale of CAINS, a 13-item, second-generation, semi-structured interview for assessing negative symptoms in schizophrenia. CONVOKE achieved study success by showing that the difference in the reduction in CAINS-MAP was statistically significant between Motivista and the Digital Control.

In the pivotal clinical study, CAINS-MAP decreased more from baseline to Week 16 in the Motivista arm (least square (LS) mean -6.8) than the Digital Control (LS mean -4.2). The -2.6 CAINS-MAP difference between the arms was statistically significant (p=0.0003). Similar outcomes were also observed in CAINS-MAP at 8 weeks with a greater reduction observed in Motivista (LS mean -5.3) than the Digital Control (LS mean -2.8) and a difference of -2.5 between arms.

The primary effectiveness results are provided in Table 3. The primary effectiveness results from the ITT analysis were supported by comparable results conducted on the mITT Set and PP Set, demonstrating the robustness of the findings.

Table 3. Primary Effectiveness Endpoint (ITT Set)

CAINS-MAP Change from Baseline to Week 16*	Motivista (N=196)	Digital Control (N=204)	Difference Between Arms
LS mean	-6.8	-4.2	-2.6
95% confidence interval (CI)	(-7.76, -5.77)	(-5.15, -3.18)	(-4.00, -1.20)
p-value	-	-	0.0003

*The primary effectiveness endpoint (change from baseline to Week 16 in CAINS-MAP total score) was analyzed using a prespecified Mixed Model Repeated Measures (MMRM) approach on the ITT set with observed data, i.e., that included subjects with at least 1 post-baseline CAINS-MAP assessment (Week 8 and Week 16). The number of participants whose longitudinal data directly inform the primary MMRM is 196 (Motivista) and 204 (Digital control). Two prespecified sensitivity analyses were conducted using the full ITT set with imputation (N=457; 227 Motivista + 230 Digital control). Missing CAINS-MAP values for all ITT participants — including the 57 with no post-baseline assessment — were multiply imputed under the MAR assumption, with the primary MMRM refit on each imputed dataset and results combined using Rubin's rule. A tipping-point analysis was also performed to evaluate robustness under a Missing Not at Random (MNAR) assumption. Both sensitivity analyses, conducted on the complete N=457 ITT population, corroborated the primary result, supporting that the treatment effect estimated from the 196/204 MMRM analysis population is representative of the full ITT population.

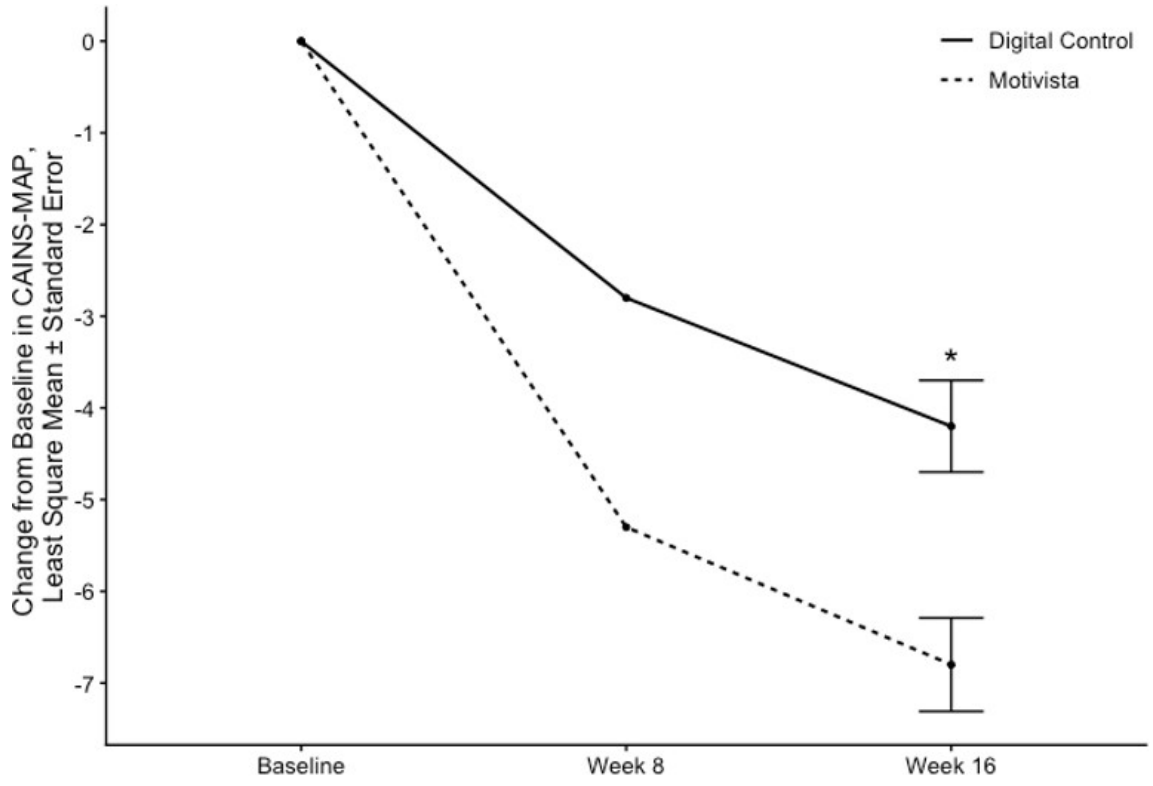

Figure 2. LS Mean Change from Baseline to Week 8 and 16 in CAINS-MAP (ITT Set)

* p-value = 0.0003

[a] Secondary effectiveness endpoints included LS mean change from CAINS-MAP Baseline to Week 8; multiplicity adjustment and hypothesis testing were excluded from the analysis of secondary endpoints.

[b] The primary effectiveness endpoint was LS mean change from Baseline to Week 16; the primary endpoint was analyzed with hypothesis testing.

5.2.7. Participant Engagement

Participant engagement data was captured by the Study Application during the pivotal clinical study in order to characterize how study participants used and interacted with Motivista and the Digital Control. The results showed high levels of participant engagement with the application, with participants on average using the application over 60% of days during the 16-week treatment period. In both arms, the average number of days with at least one daily activity completed closely mirrored the data for the number of days the Study App was used, indicating that on almost all days that participants opened the app, they meaningfully engaged. In total, participants in the Motivista arm spent approximately an hour per week using the treatment, which is comparable to the typical time spent in conventional, in-person psychotherapy (e.g., 45 to 60 minute weekly sessions). Overall, these results indicate high engagement among patients with negative symptoms of schizophrenia, and also support the face-validity (believability) of the Digital Control in the pivotal clinical study.

Table 4. Study Application Engagement Metrics (ITT Set)

	Motivista	Digital Control
Number of days the app was used, mean (%)[a]	68.5 (61.1)	80.1 (71.5)
Number of days with at least one daily activity completed, mean (%)[a,b]	66.1 (59.0)	79.2 (70.7)

[a] Percentages calculated based on total number days during Intervention Period = 112 days.
[b] Qualifying daily activities in Motivista included completing lessons, completing check-ins, practicing skill-based tool practice, and/or steps to attain goals. Daily activities in the Digital Control included completing lessons and/or completing check-ins.

5.2.8. CONVOKE Conclusions

In conclusion, data from the Motivista clinical study indicates that Motivista provides benefit to participants with negative symptoms of schizophrenia as an adjunct to standard of care antipsychotic medications. The CONVOKE pivotal clinical study, achieved study success by showing that the difference in the reduction of experiential negative symptoms as assessed by CAINS-MAP was statistically significant between Motivista and the Digital Control. There were no serious device related adverse events, and a very low incidence of suicidal ideation or behavior was observed in both arms. Although worsening psychotic symptoms that may have been related to Motivista were observed during the study, neither caused sufficient harm to cause participants to leave the study. The only study discontinuation due to suicidal ideation occurred in the Digital Control arm. Therefore, clinical evidence supports that Motivista is safe and effective for the treatment of negative symptoms in schizophrenia.

5.3. Extrapolation of Effectiveness for Patients Aged 18–21 Years

To support effectiveness in patients aged 18–21 years following the limited enrollment of this subpopulation in the Motivista's pivotal clinical study (n=4), the pediatric extrapolation frameworks were utilized (ICH E11A; FDA 2016 Pediatric Device Guidance). Full extrapolation is scientifically justified as the 18–21 age band overlaps with the peak incidence period for schizophrenia onset, and the disease course, core diagnostic criteria, and underlying pathophysiology (including motivational deficit pathways) are identical to those in older adults. Furthermore, existing clinical data in schizophrenia demonstrates that response to behavioral and pharmacological interventions is highly consistent down to adolescent populations. In Motivista's pivotal clinical study, post-hoc data from subjects aged 18–21 demonstrated directional improvements in negative symptoms (CAINS-MAP) without any device-related adverse events, suicidal ideation, or exacerbation of positive symptoms.

A dedicated pediatric risk analysis confirmed that risks in the 18–21 cohort (e.g., lower medication adherence, early-stage illness instability) represent standard disease features managed under clinician supervision rather than unique device-related harms. Because Motivista is a low-risk, non-invasive digital therapeutic, these clinical considerations are

mitigated through standard clinician-supervised care, built-in app safeguards, and updated labeling recommending clinical monitoring and caregiver involvement for patients aged 18–21.

6. Conclusions

Motivista and its predicate, Rejoyn, are both intended for use as computerized behavioral therapy devices for psychiatric disorders, as classified under 21 CFR 882.5801. The Indications for Use statement for Motivista is not identical to the predicate device and differs for the primary psychiatric diagnosis of the studied patient populations and for whom the device is intended: schizophrenia (Motivista) and Major Depressive Disorder (MDD) (Rejoyn). Motivista and Rejoyn have similar technological characteristics (provided in Table 1), including digital delivery of behavioral therapy through a smartphone application and therapeutic content that addresses a psychiatric disorder. Differences in content delivery sequence and therapy duration are due to the different intended patient populations specific to Motivista and Rejoyn.

The safety and effectiveness of Motivista are supported by the results of the CONVOKE pivotal clinical study, which was a multi-center, randomized, double-blind, digital-controlled study. The study achieved its primary objective by demonstrating a statistically significant reduction in experiential negative symptoms, as measured by the CAINS-MAP scale, with an LS mean difference of -2.6 points favoring Motivista over the Digital Control ($p=0.0003$). Motivista also demonstrated a favorable safety profile, with no serious device-related adverse events and very low incidence of suicidal ideation or behavior was observed in both arms. Although worsening psychotic symptoms that may have been related to Motivista were observed during the study, neither caused sufficient harm to cause participants to leave the study. The only study discontinuation due to suicidal ideation occurred in the Digital Control arm.

Motivista has not been studied for treating the positive symptoms of schizophrenia and is not intended for that use.

Software verification and validation testing was completed in accordance with applicable FDA guidance and demonstrates that Motivista effectively implements the behavioral model. Cybersecurity testing was also completed in accordance with applicable FDA guidance, demonstrating successful results. Software documentation demonstrates that Motivista effectively implements the behavioral therapy model.

These data reasonably demonstrate that the differences between Motivista and the predicate device do not raise new safety and effectiveness questions and Motivista is substantially equivalent to the predicate device. Motivista meets all special controls per the regulatory requirements regarding clinical data, software, and labeling for a computerized behavioral therapy device for psychiatric disorders (21 CFR 882.5801). Given the positive benefit-to-risk ratio, these data support a 510(k) clearance for Motivista as a treatment option for those suffering from negative symptoms of schizophrenia.

7. References

1. U.S. Food and Drug Administration. (2024, March 30). Premarket Notification (510(k)) K231209 for Rejoyn: Substantial Equivalence Determination. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231209.pdf