October 11, 2023

Synaptive Medical Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K232981
Trade/Device Name: Synq Software Version 1.3
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: September 21, 2023
Received: September 21, 2023

Dear Prithul Bom:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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.

Submission Number *(if known)*

K232981

Device Name

Synq Software Version 1.3

Indications for Use *(Describe)*

The Synq Software is indicated for use in conjunction with Synq, a magnetic resonance diagnostic device (MRDD) that produces axial, sagittal, coronal, and oblique cross-sectional images and displays the internal structure and/or function of the head. Depending on the region of interest, contrast agents may be used. These images when interpreted by a trained physician yield information that may assist in diagnosis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K232981

510(k) Summary

Prepared on: 2023-09-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Synaptive Medical Inc.
Applicant Address	555 Richmond St West, Suite 800 Toronto Ontario M5V 3B1 Canada
Applicant Contact Telephone	+1-647-243-3334
Applicant Contact	Mr. Ahmed Hamed
Applicant Contact Email	ahmed.hamed@synaptivemedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Synq Software Version 1.3
Common Name	Magnetic resonance diagnostic device
Classification Name	System, Nuclear Magnetic Resonance Imaging
Regulation Number	892.1000
Product Code	LNH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200327	Evry	LNH

Device Description Summary

21 CFR 807.92(a)(4)

The Synq Software allows a user to configure and initiate a magnetic resonance scan of a subject. In doing so, the software coordinates the interactions of the magnetic field, gradients, radio frequency (RF) transmitter and receiver coil in Synq (Previously known as EVRY, K200327) to produce axial, sagittal, coronal, and oblique cross-sectional images that represent the spatial distribution of protons with spin.

The Synq Software Version 1.3 upgrades the current software version in the Synq system to include additional imaging applications, functionality, and minor bug fixes.

The Software should be used only by qualified medical professionals who are trained in magnetic resonance diagnostic devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Synq Software is indicated for use in conjunction with Synq, a magnetic resonance diagnostic device (MRDD) that produces axial, sagittal, coronal, and oblique cross-sectional images and displays the internal structure and/or function of the head. Depending on the region of interest, contrast agents may be used. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use in the subject device is the same as the predicate device:

The Synq Software is indicated for use in conjunction with Synq, a magnetic resonance diagnostic device (MRDD) that produces axial,

sagittal, coronal, and oblique cross-sectional images and displays the internal structure and/or function of the head. Depending on the region of interest, contrast agents may be used. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Technological Comparison 21 CFR 807.92(a)(6)

The Subject Device is an updated version of the software in the Predicate Device and any differences are only additive and do not raise concerns on safety and effectiveness.

The substantive changes in the Subject Device are as follows:
• New pulse sequences, including:
o 3D T1 CSE ME-GRE (3D Fat Sat T1)
o 2D Spin Echo EPI
o 2D T2 CSE Spin Echo (2D Fat Sat T2)
o 3D T2 Spin Echo
o 2D Spin Echo EPI FLAIR
o 3D T2 FLAIR
o Diffusion Tensor Imaging (DTI)
o 3D T2* ME-GRE (3D SWI)

• Minor updates to existing protocols

• Updates to various SOUP/OTS packages

• Minor bug fixes

As such, functionality in the software of the Predicate Device remains substantially unchanged in the Subject Device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

As per Bench Testing document attached under Bench Testing, the image performance testing and safety testing meet all predefined acceptance criteria. Together, with an attestation from a U.S. Board certified radiologist, demonstrate substantial equivalence to the predicate device (EVRY K200327) by conforming to FDA recognized standards and addressing all requirements in FDA MRDD Guidance.
Applicable Standards and Guidance include:
NEMA MS 1
NEMA MS 2
NEMA MS 3
NEMA MS 4
NEMA MS 5
NEMA MS 8
NEMA MS 9
IEC 62464-1
IEC-60601-2-33
Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

A small, representative subset of clinical images are provided along with this 510(k) submission, as per guidance document "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" issued November 18, 2016.
Synq Software Version 1.3 did not require clinical tests since substantial equivalence to the legally marketed predicate device was proven with the verification and validation testing.

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as intended, and therefore, substantially equivalent to the legally marketed device (Evry, K200327).
Synq Software Version 1.3 did not require clinical tests since substantial equivalence to the legally marketed predicate device was proven with the verification and validation testing.