Synaptive Medical Inc.
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

April 29, 2020

Re: K200327
Trade/Device Name: Evry
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: April 20, 2020
Received: April 22, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200327

Device Name
Evry

Indications for Use *(Describe)*
Evry is indicated for use as 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.

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510(k) Summary
[As required by 21 CFR 807.92(c)]

Manufacturer: Synaptive Medical Inc.
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Canada

Establishment Registration: 3012075008

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Director, Regulatory Affairs
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Date Prepared: 27 November, 2019

Device Proprietary Name: Evry™
Classification Name: System, Nuclear Magnetic Resonance Imaging
Classification Panel: Radiology
Product Code: LNH
Regulation Number: 21 CFR 892.1000
Regulation Class: II
Regulation Description: Magnetic resonance diagnostic device

Predicate Devices:

Substantial equivalence is claimed to the following device:

Trade name	Manufacturer	510(k) Number	Date Cleared
1.5T Signa HDx family and 3.0T Signa HDx family	GE Medical Systems	K121676	September 20, 2012

Device Description	Evry is a magnetic resonance diagnostic device (MRDD) that uses a superconducting magnet to produce axial, sagittal, coronal, and oblique cross-sectional images, and displays

	the internal structure and/or function of the head. The system features various pulse sequences, imaging techniques and conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).
Indications for Use	Evry is indicated for use as 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.
Design Features/ Fundamental Scientific Technology:	Evry is based on the fundamental principle that certain atomic nuclei present in the human body can emit a weak signal when placed in a strong magnetic field. To stimulate this signal the nuclei must be excited by a radio signal at the precession frequency of the nuclei. This resonant frequency depends on the nuclei and the strength of the applied magnetic field. Emitted signals are weak radio signals at this resonant frequency which can be sampled using one or more receiver antennas and digitized for processing. Integrated into the Magnetic Resonance Imaging system are a set of gradient coils which vary the strength of the applied magnetic field as a function of position and time, and are used to spatially encode the radio signals. Computed image reconstruction algorithms are then able to convert the encoded, digitized signals into images which can then be displayed to the user. As with the predicate device, Evry includes the following technological components: • Magnet scanner unit, gradient system and RF transmit coil • Equipment room containing the equipment needed to support the scanner unit functionality • Patient Transporter • 16-Channel Receive-Only Head Coil • Patient Communication System • Operator Console

Summary of Non-Clinical Performance Data	The subject device conforms with the following FDA-recognized consensus standards and FDA guidance documents: • ISO 10993-1 Fourth edition 2009-10-15 • ANSI AAMI ISO 14971:2007/(R)2010 • ANSI AAMI ISO 15223-1:2016 • ISO 17664 Second edition 2017-10 • ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 • IEC 60601-1-2 Edition 4.0 2014-02 • IEC 60601-1-6 Edition 3.1 2013-10 • IEC 60601-2-33 Ed. 3.2 B:2015 • IEC 62304 Edition 1.1 2015-06 • ANSI AAMI IEC 62366-1:2015 • IEEE Std 3333.2.1-2015 • NEMA PS 3.1 – PS 3.20 (2016) • NEMA MS-1-2008 (R2014) • NEMA MS 2-2008 (R2014) • NEMA MS 3-2008 (R2014) • NEMA MS 4-2010 • NEMA MS 5-2010 • NEMA MS 8-2016 • NEMA MS 9-2008 (R2014) • "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" Issued November 18, 2016 • "Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Issued May 11, 2005 • "Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" – October 2, 2014 and Draft Guidance Issued October 18, 2018

	• "Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices" Issued February 3, 2016 • "Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Issued June 16, 2016 • "Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices" Issued July 11, 2016 • "Reporting of Computational Modeling Studies in Medical Device Submissions" Issued September 21, 2016 Non-clinical verification and validation tests have been performed with regards to the intended use, technical claims, requirement specifications and risk management results. Non-clinical testing included computational modeling of the integrated RF coil and gradient system demonstrating equivalence to the predicate device with respect to cardiac stimulation and RF energy deposition. The verification and validation test results demonstrate that Evry conforms with the aforementioned FDA-recognized consensus standards and guidance documents and meets the acceptance criteria. Also, a representative set of clinical images of the proposed subject device have been reviewed by a U.S. Board Certified radiologist attesting that images produced by the device are of sufficient quality for diagnostic use. Therefore, the safety and performance of Evry is substantially equivalent to the predicate device.
Clinical Testing	A direct determination peripheral nerve stimulation (PNS) volunteer study was conducted to characterize the stimulation thresholds for the purpose of deriving limits on PNS output, as outlined in IEC 60601-2-33 and "Guidance for the Submission of Premarket Notifications for Magnetic

	Resonance Diagnostic Devices". Twenty subjects were included in this study. Data from this study were used to determine PNS limits that were implemented on Evry to ensure equivalent safety against PNS compared to the predicate device.
Substantial Equivalence	Evry and the legally marketed predicate device, 1.5T Signa HDx family and 3.0T Signa HDx, family have equivalent indications, design features, fundamental scientific technology, performance and safety characteristics. While there are differences in the technological characteristics including the subject device being indicated for a subset of the predicate device indications and a lower magnetic field strength in the subject device, substantial equivalence was demonstrated with nonclinical performance (verification and validation) tests, which conformed with the requirements specified in the international and FDA-recognized consensus standards and device-specific guidance.
Conclusion	The results of the comparison of technological and safety characteristics demonstrate that the subject device is as safe and effective as the predicate and that any differences do not raise any new concerns of safety or effectiveness. In conclusion, Synaptive Medical Inc. considers the safety, performance and effectiveness of Evry to be substantially equivalent to the predicate device.