DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2017

SyntheticMR AB
% Mr. Raymond Kelly
Consultant
Licensale, Inc.
68 Southwoods Terrrace
Southbury CT 06488

Re: K162943
Trade/Device Name: SyMRI
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 22, 2017
Received: August 21, 2017

Dear Mr. Kelly:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162943

Device Name

SyMRI

Indications for Use *(Describe)*

SyMRI is a post-processing software medical device intended for use in visualization of the brain. SyMRI analyzes input data from MR imaging systems. SyMRI utilizes data from a multi-delay, multi-echo acquisition (MDME) to generate parametric maps of R1, R2 relaxation rates, and proton density (PD). SyMRI can generate multiple image contrasts from the parametric maps. SyMRI enables post-acquisition image contrast adjustment. SyMRI is indicated for head imaging. When interpreted by a trained physician, SyMRI images can provide information useful in determining diagnosis. SyMRI should always be used in combination with at least one other, conventional MR acquisition (e.g. T2-FLAIR).

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) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: August 14, 2017

Applicant:
SyntheticMR AB
Storgatan 11
SE-58223 Linköping, Sweden

Contact Person:
Raymond Kelly
68 Southwoods Terrace
Southbury, CT 06488 USA
Phone: (203) 400-7566

Device Information:
Trade Name: SyMRI® 10
Common Name: Nuclear Magnetic Resonance Imaging System
Classification: 21CFR 892.1000
Product Code: LNH
Regulatory Class: II

Predicate Device:
MAGiC K161397 (LNH)

Indications for Use

SyMRI is a post-processing software medical device intended for use in visualization of the brain. SyMRI analyzes input data from MR imaging systems. SyMRI utilizes data from a multi-delay, multi-echo acquisition (MDME) to generate parametric maps of R1, R2 relaxation rates, and proton density (PD). SyMRI can generate multiple image contrasts from the parametric maps. SyMRI enables post-acquisition image contrast adjustment. SyMRI is indicated for head imaging.
When interpreted by a trained physician, SyMRI images can provide information useful in determining diagnosis. SyMRI should always be used in combination with at least one other, conventional MR acquisition (e.g. T2-FLAIR).

Device Description

SyMRI allows the user to generate multiple image contrasts from a single acquisition scan. This is accomplished by post-processing a multi-delay, multi-echo acquisition (MDME) into parametric maps. The parametric maps are R1, R2 relaxation rates, and proton density (PD). The inverse relaxation parameters, T1 relaxation time (1/R1), and T2 relaxation time (1/R2) are also provided as parametric maps. The parametric maps can be visualized as contrast weighted MR images, such as T1, T2, PD, and Inversion Recovery (IR) weighted images (including T1-FLAIR, T2-FLAIR, STIR, Double IR, and PSIR weighted images). SyMRI calculates the pixel signal intensity as a function of R1, R2, PD, and desired MR scanner settings, such as echo time (TE), repetition time (TR), and inversion delay time (TI). A number of default settings for TE, TR, and TI are provided, but the user has the ability to change the contrast of the images. SyMRI generates all the different image contrasts from the same parametric maps, derived from the same acquisition. This leads to enhanced image slice registration, owing to the absence of inter-acquisition patient movement. SyMRI provides the user the ability to change the contrast of the images after the acquisition. This is performed by adjusting the TE, TR, and/or TI parameters post-acquisition, to generate the specific contrast desired.
SyMRI also provides image processing tools to extract the values of the parametric maps per individual pixel, per region of interest, or the entire imaging volume.

SyMRI is intended to be used on MDME sequence data from GE MAGiC.

Comparison of Technological Characteristics

SyMRI and MAGiC are the same algorithm for post processing, MAGiC also includes acquisition. Input data to SyMRI and MAGiC is MDME acquisition. SyMRI and MAGiC both uses a single scan to acquire a multi-delay, multi- echo acquisition (MDME) data to generate parametric maps of R1, R2 relaxation rates, and proton density (PD) This data is used to generate images, which are possible to adjust, even post acquisition. In SyMRI the parametric maps are used to produce the synthetic images – as in MAGiC. SyMRI is the same as MAGiC post processing.

By virtue of its intended use and physical and technological characteristics, SyMRI is substantially equivalent to the predicate devise that has been cleared for marketing in the US. The performance data shows that SyMRI is as safe and effective as the predicate device.

Performance Data Quality and Safety:

SyMRI was designed in compliance with following standards:

- AAMI/ANSI 62304- Medical Device software – Software life cycle processes
- NEMA PS 3.1 - 3.20 (2016) DICOM Format
- ISO 13485:2012 Quality management systems – Requirements for regulatory purposes
- ISO 14971:2012 Application of risk management to medical devices
- IEC 62366-1:2015 Application of usability engineering to medical devices
- IEC82304-1:2016 Health Software – Part 1: General requirements for product safety

Testing to Support of Substantial Equivalence Determination

Verification and validation was performed according to SyntheticMR processes. Additional phantom head to head comparison of R1, R2 and PD parametric maps, which included one contrast of each major synthetic image (T1w, T2w, T2 FLAIR), were performed to compare SyMRI to MAGiC. There was no difference between SyMRI and MAGiC.

Conclusion

By virtue of its intended use and physical and technological characteristics, SyMRI is substantially equivalent to the predicate device that has been cleared for marketing in the US.