



January 26, 2018

SyntheticMR AB  
% Mr. Raymond Kelly  
Consultant  
Licensale, Inc.  
68 Southwoods Terrace  
SOUTHURY CT 06488

Re: K173558  
Trade/Device Name: SyMRI  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: LNH, LLZ  
Dated: November 10, 2017  
Received: November 17, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue watermark of the letters "FDA". To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173558

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.

SyMRI is also intended for automatic labeling, visualization and volumetric quantification of segmentable brain tissues from a set of MR images. Brain tissue volumes are determined based on modeling of parametric maps from MDME images.

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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