SpinTech, Inc.
% Kay Fuller, RAC
Regulatory Affairs Consultant
30200 Telegraph Road, Suite 140
BINGHAM FARMS MI 48025

February 23, 2018

Re: K173224
Trade/Device Name: SPIN-SWI
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LLZ
Dated: January 12, 2018
Received: January 17, 2018

Dear Ms. Fuller:

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) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173224

Device Name
SPIN-SWI

Indications for Use *(Describe)*
The SpinTech, Inc. SPIN-SWI application is intended for use in the post-acquisition image enhancement of MRI acquired 3D gradient-echo images of the brain. When used in combination with other clinical information, the SPIN-SWI application may aid the qualified radiologist with diagnosis by providing enhanced visualization of structures containing venous blood such as cerebral venous vasculature.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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15. 510(k) SUMMARY

SpinTech, Inc.

SPIN-SWI Application Software

February 14, 2018

The following summary is provided pursuant to Section 513 (I) (3) (A) of the Federal Food Drug and Cosmetic Act:

1. GENERAL INFORMATION

Submitter Information: SpinTech, Inc.
30200 Telegraph Road
Suite 140
Bingham Farms, MI 48025

Contact Information: Kay Fuller, RAC
Principal Regulatory & Clinical Research Consultant
Medical Device Regulatory Solutions, LLC
734-846-7852

2. DEVICE INFORMATION

Device Name: SPIN-SWI application software

Proprietary Name: SPIN-SWI

Common Name: System, Imaging Processing, Radiological

Classification Name: Magnetic resonance diagnostic device

Classification Code: LNH, LLZ

Regulation Number: 21 CFR § 892.1000

3. PREDICATE DEVICE

The SpinTech, Inc. SPIN-SWI application device is substantially equivalent to the predicate device, Philips' SWIp application device, cleared for US commercialization via K131241 on 8/30/2013.

4. DEVICE DESCRIPTION

The SPIN-SWI device includes a post-processing algorithm that enhances the contrast of tissues with different susceptibilities from 3D gradient-echo MRI images. The susceptibility of a biological tissue relates to the concentration of iron within it, which can be present in the form of deoxyhemoglobin, ferritin, hemosiderin, or other molecules.

An MRI scan results in both magnitude and phase images. While magnitude is most commonly used clinically, the phase information can also be useful as it relates directly to the magnetic field. When tissues or objects of differing magnetic susceptibility are present, they perturb the field around them. This effect can be seen directly from phase images. While this perturbation already leads to signal loss in magnitude images, thus creating contrast, the phase information can still be used to enhance this contrast for local susceptibility changes.

Enhancing this contrast allows us to visualize structures containing venous blood such as cerebral venous vasculature that may have not been visible prior to enhancement. Some technical challenges of SWI include eliminating the effects of unwanted background fields and choosing parameters to create optimal contrast.

SPIN-SWI software works in conjunction with an FDA cleared third-party DICOM viewer as an image post-processing solution in a PC workstation. The DICOM viewer (ORIS Visual) was FDA cleared on 4/29/2010 via K100335 and is used to transmit DICOM data and display the input and output images, the SPIN-SWI software application performs the SWI post-processing on 3D GRE input images to reconstruct the SWI output images.

5. INDICATIONS FOR USE

The SpinTech, Inc. SPIN-SWI application is intended for use in the post-acquisition image enhancement of MRI acquired 3D gradient-echo images of the brain. When used in combination with other clinical information, the SPIN-SWI application may aid the qualified radiologist with diagnosis by providing enhanced visualization of structures containing venous blood such as cerebral venous vasculature.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The SPIN-SWI application's fundamental technological characteristics are similar to those of the predicate device as described in this submission, and in noted in the following table.

Feature Comparison Criteria	Subject Device SPIN-SWI K173224	Predicate Device K131241	Subject Device SE to K131241?
21 CFR Reg #, Product Code & Classification	21 CFR §892.1000 LNH, LLZ Class II	21 CFR §892.1000 LNH Class II	Yes
Regulation Name	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device	Yes
Prescription Device - Rx Only	Yes	Yes	Yes
Indications for Use	*The SpinTech, Inc. SPIN-SWI application is intended for use in the post-acquisition image enhancement of MRI acquired 3D gradient-echo images of the brain. When used in combination with other clinical information, the SPIN-SWI application may aid the qualified radiologist with diagnosis by providing enhanced visualization of structures containing venous blood such as cerebral venous vasculature.*	*SWIp is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems. It's indicated for magnetic resonance imaging of the Brain. SWIp is a technique using phase information to enhance contrast between tissues presenting susceptibility differences, such as deoxygenated blood or some mineral deposits (e.g. calcium deposits). Due to this contrast enhancement, SWIp images are sensitive for structures containing venous blood such as cerebral venous vasculature. When used in combination with other clinical information, SWIp may help the expert radiologist in the diagnosis of various neurological pathologies*	*Yes*
Intended Users	Qualified Radiologist and Technologist	Qualified Radiologist and Technologist	Yes
Type of Imaging Scans	MRI	MRI	Yes
Target Organ/System	MR Brain	MR Brain	Yes
Loading Multiple Studies	Yes	Yes	Yes
Technological Features	Supports 1.5T Images Supports 3.0T Images (Siemens MRI Systems Only)	Yes 1.5T &3.0T (Achieva & Ingenia Only)	Yes
	Filtered Phase Maps	Yes	Yes
	Minimum Intensity Projection	No	No
	Automatic High-Pass Filtering	Yes	Yes
Sterility	N/A	N/A	N/A
Biocompatibility	N/A	N/A	N/A
Electrical Safety	N/A	N/A	N/A
Thermal Safety	N/A	N/A	N/A
Energy Used/Delivered	N/A	N/A	N/A
Chemical Safety	N/A	N/A	N/A
Radiation Safety	N/A	N/A	N/A

7. NON-CLINICAL TESTING SUMMARY

The following design control, risk management and quality assurance methodologies were utilized to develop the SPIN-SWI application:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on Unit Level (Verification)
- Integration Testing (System Verification)
- Performance Testing (V&V)
- Safety Testing (V&V)
- Simulated Use Testing (Validation)

Software documentation for Moderate Level of Concern software per the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005, is also included in this premarket notification submission. The SpinTech SPIN-SWI application was tested in accordance with SpinTech's verification and validation procedures.

All predefined acceptance criteria for the engineering performance testing were met for all test cases across different imaging parameters, field strength and different subjects. The results from the pre-clinical testing performed on the SPIN-SWI application, demonstrate that the SPIN-SWI application produces results consistently according to its intended use.

8. CLINICAL TESTING SUMMARY

The subject device of this premarket notification, SPIN-SWI application, did not require clinical studies to support substantial equivalence to the predicate device.

All predefined acceptance criteria for clinical validation testing, including clinical user needs testing, as a part of the SPIN-SWI performance validation testing efforts were met across all test cases. The results of the clinical validation related testing performed on the SPIN-SWI application demonstrates acceptable image quality and that all clinical user needs are met.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The subject device and the predicate device are substantially equivalent, with respect to intended use, instructions for use, design features, technological characteristics, manufacturing methods, performance criteria, special controls, and safety and effectiveness. The subject device is substantially equivalent to the predicate device (K131241) noted herein.

10. CONCLUSION

The non-clinical and clinical testing contained herein demonstrates the SPIN-SWI application performs according to its intended use. SpinTech, Inc. considers the SPIN-SWI application software (subject device) to be substantially equivalent to the legally marketed predicate device (K131241) noted herein, and is safe and effective for its labeled intended use.