SpinTech, Inc.
% Mr. Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

June 29, 2021

Re: K210843
Trade/Device Name: STAGE
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LLZ
Dated: June 21, 2021
Received: June 22, 2021

Dear Mr. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210843

Device Name
STAGE

Indications for Use *(Describe)*

STAGE is a post-processing software medical device intended for use in the visualization of the brain. STAGE analyzes input data from MR imaging systems. STAGE utilizes magnitude and phase data acquired with specific parameters to generate enhanced T1 weighted images, susceptibility weighted imaging (SWI) images, susceptibility weighted image map (SWIM) images, pseudo-SWIM (pSWIM) images, modified pSWIM (mpSWIM) images, true SWI (tSWI) images, MR angiography (MRA) images, simulated dual-inversion recovery (DIR) images, and maps of T1, R2*, and proton density (PD).

When interpreted by a trained physician, STAGE images may provide information useful in determining diagnosis.

STAGE is indicated for brain imaging only and 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.

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15. 510(k) SUMMARY (K210843)

SpinTech, Inc.
S T A G E

510(k) Summary Preparation Date: June 28, 2021

The following summary is provided pursuant to Section 513 (l) (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: STAGE

Proprietary Name: STAGE

Common Name: System, Imaging Processing, Radiological

Classification Name: Magnetic Resonance Diagnostic Device

Classification Code: LNH / LLZ

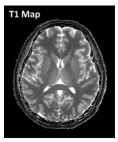
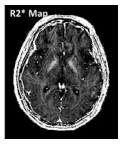
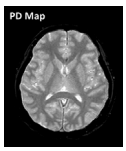
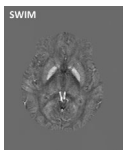
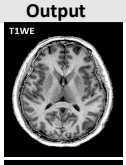
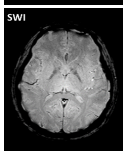
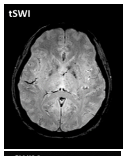
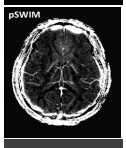
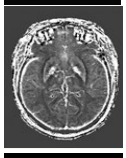
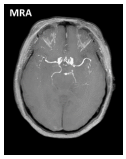
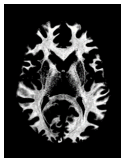
Regulation Number: 21 CFR §892.1000

3. PREDICATE DEVICE(S)

The SpinTech, Inc. STAGE software medical device is substantially similar to SyMRI software medical device cleared for US commercialization via K181093 on 6/12/2018 and the SPIN-SWI software application device cleared for US commercialization via K173224 on 2/23/2018.

4. DEVICE DESCRIPTION

STAGE works as a comprehensive brain imaging post-processing solution. The STAGE system consists of a dedicated medical grade computer (STAGE Module) connected to the user's local area network. The computer receives DICOM data from a specific MRI 3D GRE scan protocol (i.e., the STAGE protocol) and then outputs back numerous DICOM datasets with different types of contrast to the PACS server. The data transfer is initiated by the user's current DICOM viewing software. The following table provide a summary of the methodology for each output with an example image and technical comparison to the predicate.

STAGE Quantitative Output	Methodology	Technical Characteristics Comparison
Pulse Sequence	STAGE uses two or more 3D spoiled gradient echo scans collected with different flip angles.	SyMRI uses a custom spin-echo based sequence (SyMRI), collected multiple times with different parameters.
	STAGE uses a least squares fitting over variable flip angles to quantify T1.	SyMRI collects multiple scans with different delay times between a saturation pulse and acquisition to fit T1.
	STAGE uses a least squares fitting over variable echo times to quantify R2*/T2*.	SyMRI uses a least squares fitting over variable echo times to quantify R2/T2. Spin-echoes are used to get T2 rather than T2* like STAGE.
	PD maps are quantified from the same variable flip angle calculation as T1 maps, using the intercept rather than the slope of the least squares fit.	SyMRI PD maps are quantified from the same multiple delay time calculation as T1 maps.
	The SWIM output, also known as QSM in the field, has been widely used and tested in research. The STAGE version uses a weighted average iterative TKD (Threshold-based K-space Domain) approach. The phase data from each echo is unwrapped and then the background fields are removed. As a first pass, the inverse dipole kernel (the fundamental kernel used to reconstruct SWIM images) is defined using a threshold of 0.1 to estimate the ill-posed values. The veins are then thresholded out of this first pass result and their geometry is used to improve the estimation ill-posed values. This process is iterated 4 times to get a SWIM result for each echo. Last a weighted average based on R2* is used to combine all echoes to the final SWIM output.	The gold standard for QSM in the field has been COSMOS, which requires scanning the brain at multiple orientations to remove the ill-posed values in the inverse dipole kernel.
STAGE Qualitative Output	**Methodology**	**Technical Characteristics Comparison (SyMRI/SPIN-SWI)**
	To create enhanced T1W data, STAGE subtracts the PDW input data with negative WM/GM contrast from the T1W input data with positive WM/GM contrast. This is not a synthetic image calculated from the quantitative maps.	Just a conventional T1W MP-RAGE scan is the comparison to the STAGE T1WE.
	The SWI from STAGE uses the same general process: high-pass filtering the phase data, creating a mask, and applying it to the magnitude data.	SPIN-SWI (SpinTech's first FDA cleared product and current predicate for STAGE) uses the exact same algorithm for generating SWI data.
	True SWI works the same way except using iSWIM data to create a mask, helping eliminate the geometry dependence of the phase data.	The SWI data from SPIN-SWI offers the same general contrast and algorithm as the STAGE True SWI.
	Pseudo- and modified pseudo-susceptibility maps (pSWIM and mpSWIM) are created from an intensity projection of the filtered phase data. The results are not quantitative but provide similar contrast to SWIM.	SPIN-SWI (SpinTech's first FDA cleared product and current predicate for STAGE) uses the exact same algorithm for generating intensity projections.
	Pseudo- and modified pseudo-susceptibility maps (pSWIM and mpSWIM) are created from an intensity projection of the filtered phase data. The results are not quantitative but provide similar contrast to SWIM.	SPIN-SWI (SpinTech's first FDA cleared product and current predicate for STAGE) uses the exact same algorithm for generating intensity projections.
	The STAGE MRA output uses a maximum intensity projection of the T1W input data to exploit the time of flight effect of the arterial blood.	SPIN-SWI (SpinTech's first FDA cleared product and current predicate for STAGE) uses the exact same algorithm for generating intensity projections.
	Any simulated data (e.g., DIR) are created through a forward simulation process using the T1 and PD maps as input.	SyMRI forward simulates DIR data the exact same way, using the quantitative maps of T1 and PD.

5. INDICATIONS FOR USE

STAGE is a post-processing software medical device intended for use in the visualization of the brain. STAGE analyzes input data from MR imaging systems. STAGE utilizes magnitude and phase data acquired with specific parameters to generate enhanced T1 weighted images, susceptibility weighted imaging (SWI) images, susceptibility weighted image map (SWIM) images, pseudo-SWIM (pSWIM) images, modified pSWIM (mpSWIM) images, true SWI (tSWI) images, MR angiography (MRA) images, simulated dual-inversion recovery (DIR) images, and maps of T1, R2*, and proton density (PD). When interpreted by a trained physician, STAGE images may provide information useful in determining diagnosis. STAGE is indicated for brain imaging only and should always be used in combination with at least one other conventional MR acquisition (e.g., T2 FLAIR).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The STAGE fundamental technological characteristics are similar to those of the predicate devices as described herein, and as noted in the following table.

Feature Comparison Criteria	Subject Device STAGE K210843	Predicate Device A K181093 SyMRI	Subject Device Similar to K181093?	Predicate Device B K173224 SPIN-SWI	Subject Device Similar to K173224?
21 CFR Reg #, Product Code & Classification	21 CFR §892.1000 LNH / LLZ Class II	21 CFR §892.1000 LNH Class II	Yes	21 CFR §892.1000 LNH / LLZ Class II	Yes
Regulation Name	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device	Yes	Magnetic resonance diagnostic device	Yes
Prescription Device - Rx Only	Yes	Yes	Yes	Yes	Yes
Indications for Use	*STAGE is a post-processing software medical device intended for use in the visualization of the brain. STAGE analyzes input data from MR imaging systems. STAGE utilizes magnitude and phase data acquired with specific parameters to generate enhanced T1 weighted images, susceptibility weighted imaging (SWI) images, susceptibility weighted image map (SWIM) images, pseudo-SWIM (pSWIM) images, modified pSWIM (mpSWIM) images, true SWI (tSWI) images, MR angiography (MRA) images, simulated dual-inversion recovery (DIR) images, and maps of T1, R2*, and proton density (PD).* *When interpreted by a trained physician, STAGE images may provide information useful in determining diagnosis.* *STAGE is indicated for brain imaging only and should always be used in combination with at least one other conventional MR acquisition (e.g., T2-FLAIR).*	*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 indicated for automatic labeling, visualization, and volumetric quantification of segmetable brain tissues from a set of MR images. Brain tissue volumes are determined based on modeling of parametric maps from MDME.* *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 MR acquisition (e.g., T2-FLAIR).*	Yes	*The SpinTech, Inc. 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.*	Yes
Intended Users	Qualified Radiologist	Qualified Radiologist	Yes	Qualified Radiologist	Yes
Type of Imaging Scans	MRI	MRI	Yes	MRI	Yes

Feature Comparison Criteria	Subject Device STAGE K Number TBD	Predicate Device A K181093 SyMRI	Subject Device Similar to K181093?	Predicate Device B K173224 SPIN-SWI	Subject Device Similar to K173224?
Target Organ/System	MR Brain	MR Brain	Yes	MR Brain	Yes
Loading Multiple Studies	Yes	Yes	Yes	Yes	Yes
Technological Features	Supports 1.5T Images Supports 3.0T Images	Yes 1.5T & 3.0T	Yes	Yes 1.5T & 3.0T	Yes
	Filtered Phase Maps	No	Yes	Yes	Yes
	Intensity Projection	No	Yes	Yes	Yes
	Automatic High-Pass Filtering	No	Yes	Yes	Yes
	B1 correction	Yes	Yes	No	No
Output	Enhanced T1 weighted images	Yes	Yes	No	No
	SWI	No	Yes	Yes	Yes
	SWIM	No	No	No	No
	pSWIM	No	Yes	Yes	Yes
	mpSWIM	No	Yes	Yes	Yes
	tSWI (SWI algorithm)	No	Yes	Yes	Yes
	MRA (intensity projection)	No	Yes	Yes	Yes
	Simulated data (DIR, T1W, PDW)	Yes	Yes	No	No
	T1 map	Yes	Yes	No	No
	R2* map (T2=1R2*)	Yes (R2, same method)	Yes	No	No
	PD map	Yes	Yes	No	No
Pulse Sequence	3D Spoiled GRE (w/ phase data)	SyMRI	N/A	SWI	N/A
Hardware	*Minimum 16GB RAM and i7-6700TE 2.4Ghz CPU*	Minimum 4GB RAM and 1.6Ghz CPU	N/A	Minimum 8GB RAM and i7 4790k CPU	N/A
Operating System	Windows 10	Windows 10, macOS	Yes	Windows 10	Yes
Sterility	N/A	N/A	N/A	N/A	N/A
Biocompatibility	N/A	N/A	N/A	N/A	N/A
Electrical Safety	UL ANSI/AAMI ES 60601-1: 2012 (v3.1) (STAGE Module)	User Supplied PC / Console	No	User Supplied PC / Console	No
Thermal Safety	N/A	N/A	N/A	N/A	N/A
Energy Used/Delivered	N/A	N/A	N/A	N/A	N/A
Chemical Safety	N/A	N/A	N/A	N/A	N/A
Radiation Safety	N/A	N/A	N/A	N/A	N/A

Once tissue NMR parameters are quantified (in the form of T1, PD, T2 or T2 maps), this information can be used to simulate what other MRI scans would look like. SyMRI uses this information to simulate simple spin-echo scans at different user-specified imaging parameters, while STAGE uses this information to simulate dual-inversion-recovery data and the input spoiled gradient-echo data.

7. NON-CLINICAL TESTING SUMMARY

The following design control, risk management and quality assurance methodologies were utilized to develop STAGE:

- 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. STAGE was tested in accordance with SpinTech's verification and validation procedures.

All predefined acceptance criteria for the engineering (pre-clinical) performance testing were met. The results from the pre-clinical testing performed on STAGE produced results consistently according to its intended use.

8. CLINICAL TESTING SUMMARY

A reader study was conducted to demonstrate acceptable diagnostic image quality and equivalent radiologic finding classes compared to the predicate device. All predefined acceptance criteria for clinical validation testing included clinical user needs testing, as a part of the STAGE performance validation testing efforts were met across all test cases. The results of the clinical validation related testing performed on STAGE demonstrated acceptable image quality and that all clinical user needs were met.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The subject device and the predicate devices 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 devices (K181093 and K17324) noted herein.

10. CONCLUSION

The non-clinical and clinical testing contained herein, demonstrates that STAGE performs according to its intended use. The SpinTech, Inc. considers the STAGE (subject device) to be substantially equivalent to the legally marketed predicate devices noted herein.