October 28, 2022

SpinTech, Inc.
℅ Rana Hachem
Management Representative / Business Operations Manager
30200 Telegraph Road
Suite 140
BINGHAM FARMS MI 48025

Re: K223079
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: September 28, 2022
Received: September 30, 2022

Dear Rana Hachem:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*

K223079

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 Tl 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 Tl, 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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510(k) Summary

Date Prepared: September 28, 2022

Submitter:
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Bingham Farms, MI 48025

Contact:
Rana El Hachem
Management Representative / Business Operations Manager
SpinTech, Inc.
(248) 712-6789
rana@ spintechmri.com

Proprietary Name: STAGE

Common Name: System, Imaging Processing, Radiological

Classification Name: Magnetic resonance diagnostic device

Regulation Number: 21 CFR Section 892.1000

Classification Code: LNH / LLZ

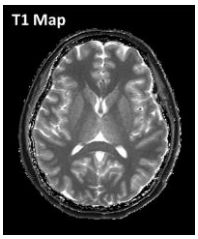
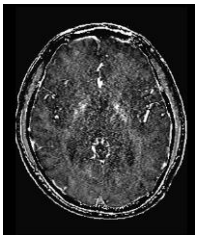
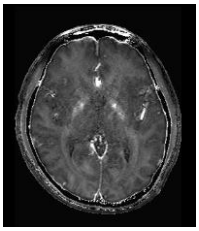
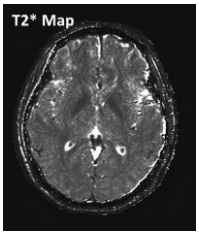
Review Panel: Radiology

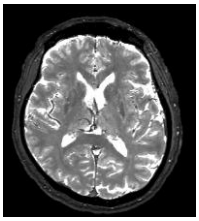
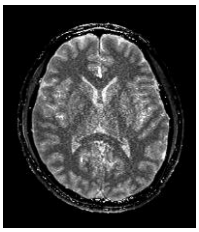
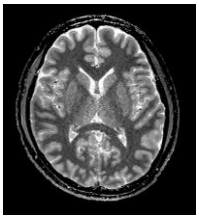
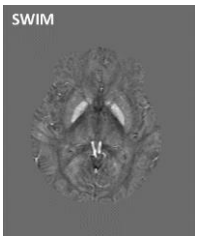
Substantially Equivalent Devices: K210843 – SpinTech, Inc. STAGE

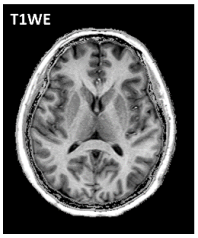
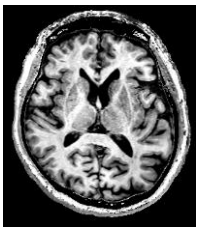
Device Description:

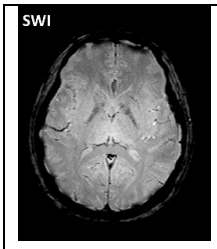
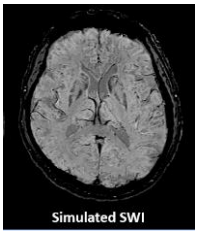
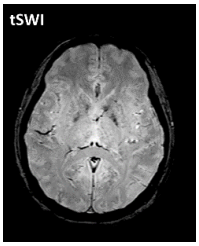
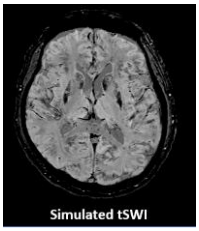
STAGE works as a comprehensive brain imaging post-processing solution. The STAGE system consists of a client supplied dedicated computer with an ethernet connection to the client's existing local network. The STAGE software will operate within a virtual machine environment (virtual STAGE module) on this dedicated computer. 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. STAGE has been modified from the predicate to include

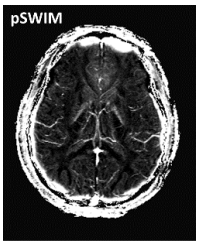
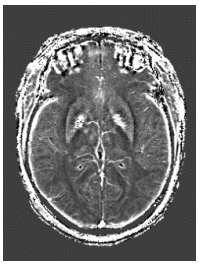
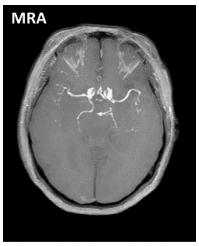
CROWN, a white noise filtering algorithm intended to improve specific STAGE outputs. The following table provide a summary of the methodology for each output with an example image and technical comparison to the predicate.

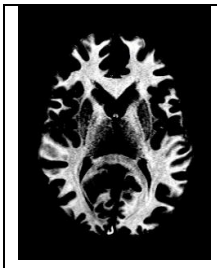
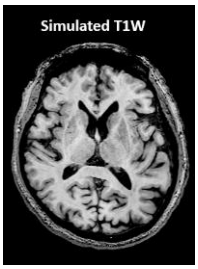
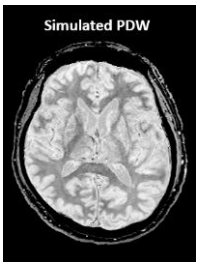
STAGE Quantitative Output	Output Methodology	Technical Characteristics Comparison
T1 Map 	STAGE uses a least squares fitting over variable flip angles to quantify T1. Expected Contrast: WM, GM, CSF contrast will appear similar to a conventional T2W scan. Comparable Conventional Scan Contrast: T1W (inverted)	Methodology Unchanged
R2* Map  CROWN enabled R2* Map 	STAGE uses a least squares fitting over variable echo times to quantify R2*/T2*. The optional CROWN filter is compatible with R2* Map. Expected Contrast: Veins and midbrain GM structures and cortical GM should be bright relative to surrounding tissues. Diamagnetic tissue (major WM tracts, calcifications) should also appear bright. Comparable Conventional Scan Contrast: SWI /SWAN (inverted)	Methodology Unchanged CROWN functionality available for alternate R2* Map output.
T2* Map 	STAGE calculates T2* by simply taking the inverse from the quantified R2* result. The optional CROWN filter is compatible with T2*Map. Expected Contrast: Veins and midbrain	Methodology Unchanged CROWN functionality available for alternate T2* Map output.

CROWN enabled T2* Map  *different patient scans	GM structures and cortical GM should be dark relative to surrounding tissues. Diamagnetic tissue (major WM tracts, calcifications) should also appear dark. Comparable Conventional Scan Contrast: SWI /SWAN	
PD Map  CROWN enabled PD Map 	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. The optional CROWN filter is compatible with PD Map. Expected Contrast: WM, GM, CSF contrast will appear similar to a conventional T2W scan. However veins and midbrain GM structures and cortical GM should be slightly darker relative to surrounding tissues. Comparable Conventional Scan Contrast: PDW	Methodology Unchanged CROWN functionality available for alternate PD Map output.
Susceptibility weighted image mapping (SWIM) 	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	Methodology Unchanged

	echoes to the final SWIM output. Expected Contrast: Veins and midbrain GM structures and cortical GM should be bright relative to surrounding tissues. Diamagnetic tissue (major WM tracts, calcifications) should appear dark. Comparable Conventional Scan Contrast: SWI /SWAN (inverted)	
STAGE Qualitative Output		
T1 Weighted Enhanced (T1WE)  CROWN enabled T1 Weighted Enhanced (T1WE)  *different patient scans	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. The optional CROWN filter is compatible with T1WE. Expected Contrast: This output should appear like a conventional T1 weighted anatomical scan. Comparable Conventional Scan: MPRAGE	Methodology Unchanged CROWN functionality available for alternate T1WE output.
Susceptibility weighted imaging (SWI)	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. The optional CROWN filter is compatible with SWI.	Methodology Unchanged CROWN functionality available for alternate SWI output.

 CROWN enabled Susceptibility weighted imaging (SWI)  *different patient scans	Expected Contrast: Veins and midbrain structures should appear dark relative to surrounding tissues. Diamagnetic tissue (major WM tracts, calcifications) should also appear dark. Comparable Conventional Scan: SWI /SWAN	
True Susceptibility weighted imaging (tSWI)  CROWN enabled True Susceptibility weighted imaging (tSWI) 	True SWI works the same way except using iSWIM data to create a mask, helping eliminate the geometry dependence of the phase data. The optional CROWN filter is compatible with tSWI. Expected Contrast: Veins and midbrain structures should appear dark relative to surrounding tissues. Diamagnetic tissue (major WM tracts, calcifications) should also appear dark. Comparable Conventional Scan Contrast: SWI /SWAN	Methodology Unchanged CROWN functionality available for alternate tSWI output.

*different patient scans		
Pseudo SWIM (pSWIM) 	Pseudo-susceptibility map (pSWIM) is created from an intensity projection of the filtered phase data. The results are not quantitative but provide similar contrast to SWIM. Expected Contrast: Veins and midbrain GM structures and cortical GM should be bright relative to surrounding tissues. Comparable Conventional Scan Contrast: SWI /SWAN MIP (inverted)	Methodology Unchanged
Modified pSWIM (mpSWIM) 	Modified pseudo-susceptibility map (mpSWIM) are created from an intensity projection of the filtered phase data. The results are not quantitative but provide similar contrast to SWIM. Expected Contrast: Veins and midbrain GM structures and cortical GM should be bright relative to surrounding tissues. Highly diamagnetic tissue (calcifications) should appear dark. Comparable Conventional Scan Contrast: SWI /SWAN MIP (inverted)	Methodology Unchanged
Magnetic resonance angiography (MRA) 	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. Expected Contrast: Arterial blood flowing into the imaging slab should be bright. Other tissues should show little to no contrast. Comparable Conventional Scan Contrast: TOF MRA	Methodology Unchanged
Simulated Synthetic dual inversion recovery (DIR)	Any simulated data (e.g., DIR) are created through a forward simulation process using the T1 and PD maps as input. The optional CROWN filter is compatible	Methodology Unchanged

	with simulated DIR. Expected Contrast: For the three DIR outputs, either GM, WM, or CSF alone will be bright and the rest will be dark. Comparable Conventional Scan Contrast: Dual Inversion Recovery	
Simulated T1W 	Any simulated data are created through a forward simulation process using the T1 and PD maps as input. Expected Contrast: For the three DIR outputs, either GM, WM, or CSF alone will be bright and the rest will be dark. Comparable Conventional Scan Contrast: Dual Inversion Recovery	Methodology Unchanged CROWN functionality available for alternate simulated T1W output.
Simulated PDW 	Any simulated data are created through a forward simulation process using the T1 and PD maps as input. Expected Contrast: For the three DIR outputs, either GM, WM, or CSF alone will be bright and the rest will be dark. Comparable Conventional Scan Contrast: Dual Inversion Recovery	Methodology Unchanged CROWN functionality available for alternate simulated PDW output.

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 Tl 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 Tl, 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).

Comparison of Technological Characteristics:

The STAGE fundamental technological characteristics are similar to those of the predicate device as noted in the following table.

Characteristic	Predicate Device STAGE (v. 1.1) SpinTech, Inc. (K210843)	Proposed Device STAGE (v 2.0 incl. CROWN) SpinTech, Inc. (TBD)	Similarities and Differences
Classification	Class II	Class II	Identical
Regulation	21 CFR 892.1000	21 CFR 892.1000	Identical
Regulation Name	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device	Identical
Product Code	LNH LLZ	LNH LLZ	Identical
Prescription	Rx only	Rx only	Identical
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 Tl 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 Tl, 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	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 Tl 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 Tl, 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	Identical

	imaging only and should always be used in combination with at least one other conventional MR acquisition (e.g., T2 FLAIR).	imaging only and should always be used in combination with at least one other conventional MR acquisition (e.g., T2 FLAIR).	
Intended Users	Qualified Radiologist	Qualified Radiologist	Identical
Type of Imaging Scans	MRI	MRI	Identical
Target Organ/System	MR Brain	MR Brain	Identical
Loading Multiple Studies	Yes	Yes	Identical
Technological Features	Supports 1.5T Images Supports 3.0T Images	Supports 1.5T Images Supports 3.0T Images	Identical
	Filtered Phase Maps	Filtered Phase Maps	Identical
	Intensity Projection	Intensity Projection	Identical
	Automatic High-Pass Filtering	Automatic High-Pass Filtering	Identical
	B1 Correction	B1 Correction	Identical
	N/A	CROWN	Difference
Output Map	Enhanced T1 weighted images	T1 weighted images T1 weighted images with white noise reduced via CROWN	Similar
	SWI	SWI SWI with white noise reduced via CROWN	Similar
	SWIM	SWIM	Identical
	pSWIM	pSWIM	Identical
	mpSWIM	mpSWIM	Identical
	tSWI (SWI algorithm)	tSWI tSWI with white noise reduced via CROWN	Similar
	MRA (intensity projection)	MRA	Identical
	Simulated data (DIR, T1W, PDW)	DIR T1W PDW DIR, T1W, and PDW with white noise reduced via CROWN	Similar
	T1 map	T1 map	Identical
	R2* map (T2=1R2*)	R2* map R2* map with white noise reduced via CROWN	Similar
	PD map	PD map PD map with white noise	Similar

		reduced via CROWN	
Pulse Sequence	3D Spoiled GRE (w/ phase data)	3D Spoiled GRE (w/ phase data)	Identical
Hardware	CPU – i7-6700TE 2.4Ghz (minimum) RAM – 16 GB (minimum)	STAGE 2.0 is a Software Only device. Hardware provided by the client must meet the following minimum requirements: CPU – 6 cores 2.1GHz (minimum), 8+ cores 2.6GHz (recommended) RAM – 16GB (minimum) Disk Space – 128GB (minimum)	Difference
Operating System	Windows 10	Windows 10	Identical
Sterility	N/A	N/A – Software only device	Similar
Biocompatibility	N/A	N/A – Software only device	Similar
Electrical Safety	UL ANSI/AAMI ES 60601-1: 2012 (v3.1) (STAGE Module)	N/A – Software only device	Difference
Thermal Safety	N/A	N/A	Identical
Energy Used/Delivered	N/A	N/A	Identical
Chemical Safety	N/A	N/A	Identical
Radiation Safety	N/A	N/A	Identical

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, was established and maintained for STAGE. STAGE was tested in accordance with SpinTech's verification and validation procedures.

All predefined acceptance criteria for the performance testing were met. The results from the performance testing executed on STAGE produced results consistently according to its intended use.

Clinical Testing Summary:

Clinical testing was not necessary to demonstrate substantial equivalence of STAGE to the predicate device.

Conclusions Drawn from Non-Clinical Tests:

The subject device and the predicate devices are substantially equivalent, with respect to intended use, instructions for use, design features, technological characteristics, performance criteria, and safety and effectiveness. The subject device is substantially equivalent to the predicate device, K210843.

Conclusion:

The non-clinical software testing performed on STAGE demonstrates that STAGE performs according to its intended use. SpinTech, Inc. considers STAGE (subject device) to be substantially equivalent to the legally marketed predicate device, K210843.