DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2016

Hitachi Medical Systems America, Inc.
% Mr. Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K162079
Trade/Device Name: TRILLIUM OVAL Head Coil 32
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 28, 2016
Received: July 29, 2016

Dear Mr. Thistlethwaite:

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 yours,

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)*
K162079

Device Name
TRILLIUM OVAL Head Coil 32

Indications for Use *(Describe)*
The TRILLIUM OVAL Head Coil 32 is a 32 channel recieve-only multiple array device used with the Hitachi TRILLIUM OVAL 3.0 Tesla systems for imaging of the head region that can be interpreted by a trained physician.

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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Section 5

510(k) Summary

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
Registration Number:	1528028
Contact:	Douglas J. Thistlethwaite
Telephone number:	330-425-1313
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Date:	July 11, 2016

Manufacturer Information

Manufacturer:	HITACHI, LTD. 2-1, Shintoyofuta Kashiwa-shi, Chiba-Ken, Japan 277-0804
Registration Number:	8030405

Device Information

Regulation Number:	892.1000
Regulation Name:	Coil, Magnetic Resonance, Specialty
Product Code	MOS
Class	2
Panel	Radiology
Trade/Proprietary Name:	TRILLIUM OVAL Head Coil 32
Predicate Device(s):	TRILLIUM OVAL WIT Posterior Head/Neck coil and WIT Anterior Head attachment (K142734)

Device Intended Use

The TRILLIUM OVAL Head Coil 32 is a 32 channel recieve-only multiple array device used with the Hitachi TRILLIUM OVAL 3.0 Tesla systems for imaging of the head region that can be interpreted by a trained physician.

Device Description

Function

The TRILLIUM OVAL Head Coil 32 is a receive-only device that detects the MR signal used to produce transverse, coronal, sagittal, oblique, and/or curved cross-sectional images that display the internal structure of the head. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Scientific Concepts

Magnetic Resonance imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector.

The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2. A RF emission or echo that can be measured accompanies these relaxation events.

The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

Physical and Performance Characteristics

The Head Coil 32 is used with TRILLIUM OVAL MRI System. The coil consists of 32 elements multiple array coils used for obtaining diagnostic images of the human head region in MRI System.

The MRI system produces images by using the transmitter coil. Head Coil 32 is used as receiver in the system. The use of transmitter coil ensures uniform volume excitation, while the receiver coils enhance the reception sensitivity or S/N ratio for optimal image quality.

Performance Evaluation

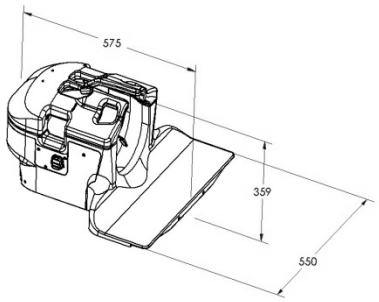
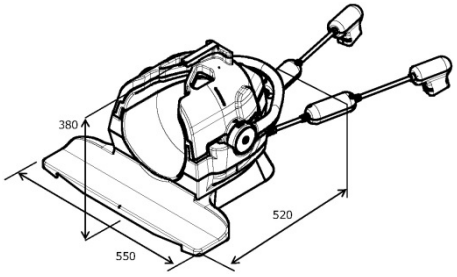
Quality assurance measures were conducted on the subject device. Testing included:

- NEMA MS 1
- NEMA MS 3
- Heat testing
- AAMI / ANSI ES60601-1
- IEC 60601-1-2
- IEC 60601-2-33

Device Technological Characteristics

The technological characteristics (intended use, hardware, and performance) of the subject device are very similar to the predicate device as indicated in Table 1.

Table 1 Head Coil 32 Predicate Comparison Table

Parameter		Predicate Device: WIT Posterior Head/Neck coil and WIT Anterior Head attachment	Subject Device: Head Coil 32
Intended Use	Indications for Use Statement	The WIT Posterior Head/Neck coil with WIT Anterior Head attachment is recieve-only multiple array device used for MRI imaging of the head region.	The TRILLIUM OVAL Head Coil 32 is a recieve-only multiple array device used for MRI imaging of the head region.
Dimensions	Coil length	575 mm	520 mm
	Coil height	359 mm	380 mm
	Coil width	550 mm	550 mm
	Figure		
Coil Architecture	Coil type	Receive only, 15 channel	Receive only, 32 channel
	Housing type	Rigid	Rigid
	Coil Elements	19 Element	32 Element
	Primary Decoupling	Active and passive	Active and passive
Performance	NEMA MS 1 Method 4	145 +/- 20%	245 +/- 20%
Electrical Safety	Electrical safety standards applied	UL-60601-1	UL-60601-1
	Safety Class (IEC 60601-1)	Class II	Class II
	Waterproof	No	No
	Explosion proof	No	No
Labeling	Operator's Manual	WIT Posterior Head/Neck coil Instruction Manual	Head Coil 32 Instruction Manual

The technological differences from the TRILLIUM OVAL Head Coil 32 to the predicate device are analyzed in Table 2.

Table 2 Differences Analysis

FDA Requirements	Analyze why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)). 21 CFR 807.87(f)).			
Device Modification Summary	Coil was designed with 32 channels.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	The performance and technological characteristics of coil are similar to the predicate device.			

There are no functionality differences from the TRILLIUM OVAL Head Coil 32 to the predicate device as analyzed in Table 3.

Table 3 Functionality Comparison Analysis

FDA Requirements	Analyze why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).			
Device Modification Summary	None			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	There is no new intended use.			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: TRILLIUM OVAL V5.1 MRI vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.
Functionality	Enhanced features do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed TRILLIUM OVAL Head Coil 32 is considered substantially equivalent to the currently marketed predicate device.

Summary of Non-Clinical Testing

The TRILLIUM OVAL Head Coil 32 is in conformance with the applicable parts of the following standards:

- NEMA MS 1-2008, Determination of Signal-to-noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012, c1:2009/(r) 2012 and a2:2010/(r) 2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 60601-2-33 Edition 3.1 2013-04, medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic.

In addition, heat testing was conducted on the new TRILLIUM OVAL Head Coil 32.

Summary of Clinical Testing

No clinical tests were conducted to support the TRILLIUM OVAL Head Coil 32 and the substantial equivalence conclusion. However, clinical images of the head were provided to support the effectiveness of the subject device.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the TRILLIUM OVAL Head Coil 32 has the same intended use and the same basic technological characteristics as the predicate device. While there are some technical features that vary with respect to the predicate device, the conclusions from the non-clinical data suggest that the subject device bears an equivalent safety and performance profile as that of the predicate device.

Therefore, the TRILLIUM OVAL Head Coil 32 is substantially equivalent to the predicate device.