510(k) Summary

3T 32 Channel Head Coils

K182737

1. **Submission Sponsor**

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3. **Date Prepared**

   April 9, 2019

4. **Device Identification**

   Trade/Proprietary Name: 3T 32 Channel Head Coils

   - Model 3832016 is compatible with GE MRI Scanner Discovery MR750;

- Model 38320169 is compatible with GE MRI Scanners SIGNA Architect, Discovery MR750W and SIGNA PET/MR.

Common/Usual Name:	MRI Head Coils
Classification Name:	Magnetic Resonance Diagnostic Device, Accessory
Regulation Number:	892.1000
Product Code:	MOS
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device and Reference Device

Predicate Device: K072931; MC 3003G - 32 R Head Coil; MR Instruments Inc.

Reference Device: K142098; SIGNA PET/MR with 3.0T HNU Coil; GE Medical Systems, LLC

6. Indication for Use Statement

The Nova Medical 3T 32 Channel Head Coil is to be used in conjunction with a Magnetic Resonance (MR) Scanner to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.
Model # 3832016 is used with GE 3T MRI Scanner Discovery MR750.
Model # 38320169 is used with GE 3T MRI Scanners Signa Architect, Discovery MR750W and Signa PET/MR.

7. Device Description

The Nova Medical 3T 32 Channel Head Coil is receive only MR coil for imaging the human head when used with GE Healthcare 3T MR Systems. The head coil has 32 RF elements that are tuned to 127.75 MHz. The head coil is constructed of a two part rigid plastic housing with an opening for patient viewing and comfort. The 3T 32 Channel Head Coil comprises a split design for easy patient positioning, measures approximately 17.5” long x 12” high x 15” wide without the tray and has an approximate weight of 20 lbs. The device comes with optional accessories; Mirror for patient viewing and Foam Cushions for patient comfort and head positioning.

8. Substantial Equivalence Discussion

The following table compares the Nova Medical, Inc. 3T 32 Channel Head Coil to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Nova Medical**	**MR Instruments**
Trade Name	**3T 32 Channel Head Coil** **(3T 32 CH Head Coil)**	**MC 3003G-32R Head Coil**
510(k) Number	K182737	K072931
Attribute		
Product Classification	Class II	Class II
Product Code	MOS	MOS
Regulation Number	892.100	892.100
Regulation Name	Magnetic Resonance diagnostic device	Magnetic Resonance diagnostic device
Indications for Use	The Nova Medical 3T 32 Channel Head Coil is to be used in conjunction with a Magnetic Resonance (MR) Scanner to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis. Model # 3832016 is used with GE 3T MRI Scanner Discovery MR750. Model # 38320169 is used with GE 3T MRI Scanners Signa Architect, Discovery MR750W and Signa PET/MR.	The MR Instrument MC 3003G-32R Head Coil is to be used in conjunction with a MR Scanner to produce images and /or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.
Channel Array / Coil Type	32 Channel Whole-Brain Receive-only Array	32 Channel Whole-Brain Receive-only Array
Application	High Sensitivity Neuroimaging/ fMRI/spectroscopy	High Sensitivity Neuroimaging/ fMRI/spectroscopy
Conditions of Use	Model # 3832016 is used with GE 3T MRI Scanner Discovery MR750. Model # 38320169 is used with GE 3T MRI Scanners Signa Architect, Discovery MR750W and Signa PET/MR.	Use with GE Discovery MR750 Scanner
Maximum Static Field	3T	3T

Manufacturer	Nova Medical	MR Instruments
Trade Name	**3T 32 Channel Head Coil** **(3T 32 CH Head Coil)**	**MC 3003G-32R Head Coil**
RF (nominal)	127.75 MHz	127.8 MHz
Resolution	Scanner Sequence Dependent	Scanner Sequence Dependent
Size	Head Coil dimensions: • Outside Housing width 25.7 cm • Inside Housing width 18 cm • Outside Housing height 27.6 cm • Inside Housing height 22 cm Head Coil with Tray dimensions: • Coil Length 38.5 cm • Coil Width 44 cm • Coil Height 29.25 cm Weight - 20 lbs. including the Tray	• Inner Dimensions – 23.5cm • Coil Size – 29cm W x 30cm L • Coil Base – 41cm W x 48cm L • Weight – 6.8kg with base
Shape	Rigid plastic, cylindrical case, with an opening for patient viewing and tray	Rigid plastic, cylindrical case with an opening for patient viewing
Anatomical Location	Head	Head
Patient population (including age, anatomy)	All ages and body types	All ages and body types
Housing Materials	Plastic	Plastic
Duration of Body Contact	Generally between 20 min. – 1 hour	Generally between 20 min. – 1 hour
Software Microprocessor	No	No
Complies with ISO 10993-1	Yes	Unknown
Electrical Safety Testing	ANSI/AAMI ES 60601-1 IEC 60601-2-33 IEC 61000-4-2 per IEC 60601-1-2	Unknown

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of 3T 32 Channel Head Coils and in showing substantial equivalence to the predicate device, Nova Medical, Inc. completed a number of non-clinical performance tests. The 3T 32 Channel Head Coils meet all the requirements for overall design, performance, biocompatibility, and electrical safety, confirming that the design output meets the design inputs and specifications for the device.

Reference Device, K142098 (SIGNA PET/MR with 3.0T HNU Coil; GE Medical Systems, LLC), was a device used along with the Nova Medical 3T 32 Channel Head Coil for a study performed on GE SIGNA PET/MR, which is part of the 'Performance Testing' referenced below.

The 3T 32 Channel Head Coils passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1
- Electrical safety testing per IEC 60601-1
- Electrostatic discharge testing per IEC 61000-4-2 (per IEC 60601-1-2).
- Safety & essential performance of magnetic resonance equipment per IEC 60601-2-33
- Magnetic Resonance Diagnostic Devices Testing per NEMA MS 6
- Transport Testing per ISTA Procedure 2B
- Performance Testing: A number of performance tests were performed by Nova Medical, Inc. as part of the design and development process; results were deemed acceptable.

10. Clinical Performance Data

Clinical images were obtained in accordance with the FDA Guidance (November 18, 2016) for Submission of Premarket Notification for Magnetic Resonance Diagnostic Devices. The clinical images were deemed to be of acceptable image quality and were certified by a Chief Medical Physicist.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The Nova Medical, Inc. 3T 32 Channel Head Coils, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.