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Proprietary or Trade Name: MRI Multi-Channel Optical Communication System (MOC)

Common/Usual Name: System, Nuclear Magnetic Resonance Imaging (Accessory)

Classification Name: System, Nuclear Magnetic Resonance Imaging (Accessory)
 Product code – LNH
 21 CFR 892.1000
 Class II

Predicate Devices: fMRI Hardware System, Nuclear Magnetic Resonance Imaging System (NordicNeuroLab AS.) K073099
 Silent Scan, Nuclear Magnetic Resonance Imaging (Avotec Inc) K921891

Device Description:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs. The MRI MOC comprises the following main component devices:

Component	Description
IMROC	IMROC is a two-way optical communication device that enables multi-channel dialogs in real time between the MRI Patient, medical Staff and technologists. Communication transmission is based solely on fiber optic cables. IMROC also enables the Patient to listen to music and/or other audio stimulation (e.g., voice commands from the Scanner computer or personnel) during a Scanning session.
IMROC IR Wireless	IMROC IR Wireless is identical in design and function to the IMROC, except that communication transmission is based on wireless infrared (IR) technology as well as fiber optic cables. There are no active components in this device, there are no patient applied parts.
OptoACTIVE	OptoACTIVE is a real-time active noise-cancelling headset that enables two-way communications with the MRI Patient or with MRI Staff while significantly reducing MRI EPI main gradient noise and providing excellent sound quality. OptoACTIVE also enables the Patient to listen to music and/or other audio stimulation (e.g., voice commands from the Scanner computer or personnel) during a Scanning session.

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Sub-Component Devices

The MRI MOC System devices include the following sub-component devices:

Sub-Component	Description
Optical Headsets	<p>Each Headset includes left-and-right high fidelity optical speakers inside a passive noise-reducing casing, coupled with a dual-channel noise-cancelling optical microphone and enables full duplex communications among Staff and Patient. The Headset is fitted with noise-reducing disposable earpads.</p> <ul style="list-style-type: none"> • <u>IMROC/IMROC IR Wireless</u> • <u>OptoACTIVE</u> – The Headset interfaces directly with the System EOU via fiber optic cable. The Headset is available in an optional Ultra-Slim form factor, designed for use in 32-channel head coils.
Control/Mixing Console	<p>The Control and Mixing Console is operated by the technologist in the Control Room to manage the interactive communications environment (e.g., turning off specific headsets, muting Staff/Patient's speaker, adjusting noise cancelling and noise reduction levels, Patient's music volume, etc.).</p> <p>The Console features an MP4 format player to enable selection of appropriate music for a Patient. In addition, the Console enables direct music input from a compatible external player, brought by a Patient.</p> <p>The Console contains a built-in microphone and speaker for direct communications between the technologist and the medical Staff. The Console contains electronic parts and is attached directly to the EOU via electrical cable.</p>
Electro-Optical Unit (EOU)	<p>The Electro-Optical Unit (EOU) is the main processing unit of the System. It receives inputs from the optical Headsets, performs required optical to electrical signal transduction, noise-cancelling and signal enhancement processing, and redistributes communications to Staff and Patient according to current settings on the Control/Mixing Console.</p>
IR Transceiver Unit	<p><i>(IMROC IR Wireless Component Only)</i> A stationary, wall-mounted unit in the Scanner Room which exchanges wireless infrared (IR) signals with the Optical Headsets of each Staff member. It interfaces with the System EOU via fiber optic cable.</p>
Battery Recharging Unit	<p><i>(IMROC IR Wireless Component Only)</i> A stationary, tabletop unit that is intended to be used in the Control Room, where it is easily accessible to Staff responsible for routine System operation. It recharges batteries that are used in the Personal Control Unit, as required. Multiple batteries can be recharged simultaneously.</p>
Hygienic Pop Screens	<p>Specially-fitted pop-screens can be attached to the microphone on the Optical Headset. The screens are designed to be used once per Scanning session, and are disposable.</p>
Hygienic Earpad Covers	<p>Industry standard disposable earpad covers are mounted on left and right earphones on the Optical Headset and are disposable.</p>

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Indications for Use:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.

Patient Population:

The MOC System is designed and intended for use by Patients undergoing functional, interventional and clinical MRI scans. As described above, the System is also used by Doctors and Technologists in these environments.

Environment of Use:

The MOC System is designed and intended for use only in functional, interventional and clinical MRI environments.

Contraindications:

There are no special precautions, warnings or contraindications for using the MOC System.

Comparison to Predicates and Substantial Equivalence:

The following table provides a comparison of the proposed device to the predicates.

The MRI Multi-Channel Optical Communication (MOC) System is viewed as substantially equivalent to the predicate devices because:

Indications – Equivalent to predicates – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Technology – Equivalent technology and design – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Performance – Equivalent to the predicates – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Performance Testing –

A comprehensive performance testing and evaluation program was developed in order to verify that the MRI MOC System meets its specifications and does not raise any new safety and effectiveness issues in comparison to the predicate devices. The main parts of the testing program were:

- The Electrical Safety and Electromagnetic compatibility of the MOC were tested by external laboratories and testing results demonstrate that the System is in compliance with the requirements of the IEC 60601-1 (and amendments), and IEC 60601-1-2 standards.
- Comprehensive performance evaluation studies were conducted to ensure that the MOC meets its specifications.

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- Comprehensive clinical performance studies were conducted to ensure that the MOC performs effectively, in full accordance with its indications and intended use.
- Risk analysis activities were conducted in accordance with requirements of ISO 14971 “Medical devices – Application of risk management to medical devices” (2007). As concluded from the Risk Analysis procedure, the potential risks of the MOC have been reduced to pre-determined acceptance criteria and the residual risk deemed acceptable.
- Based on these performance testing results, as well the verification and validation processes and an analysis of the similarities and differences presented above, it can be concluded that the MOC is substantially equivalent to the predicate devices without raising new issues of safety or effectiveness.

Conclusion

The MRI Multi-Channel Optical Communication (MOC) System is substantially equivalent to the predicates NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

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Manufacturer	Optoacoustics Ltd	NordicNeuroLab AS	Avotec
Description	MRI Multichannel Optical Communication Systems for MRI (MOC)	fMRI Hardware System, Nuclear Magnetic Resonance Imaging System	Silent Scan – (Hearing Protection and Communication System)
Device Manufacturer	Optoacoustics Ltd.	NordicNeuroLab AS.	Avotec, Inc.
Intended Use	The MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.	The fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR Imaging (fMRI) based on Blood Oxygen Level Dependant (BOLD) contrast.	Silent Scan is a hearing protection and communication system intended to provide two-way audio communications and a music listening experience to patients during MR imaging sessions.
Intended Population	The device is intended for use during the MRI procedures as a communication accessory (Patient, Radiologist, Technologists)	The device is intended for use during the MRI procedures as a communication accessory. (subject in fMRI brain studies, not clinical)	The device is intended for use during the MRI procedures as a communication accessory (Patient, Radiologist, Technologists)
Location of Use	Hospital environment (MRI facilities)	Hospital environment (MRI facilities)	Hospital environment (MRI facilities)
Core Technology	Optical Laser, Optical Transduction (converting light modulation to sound), Diffuse Infrared (IR)	Electrostatic Headphone with Electrical Cable	Pneumatic Audio Transmission with Piezo-Electronics Driver
System Components	Patient Optical Headset Staff Optical Headsets Control/Mixing Console Electro-Optical Unit (EQU) IR Transceiver Wall Units Fiber Optic Cables Battery Recharger	Patient Headset Mixing Console Electronic Amplifier Electrical Cables	Patients Headsets Electronic Communication Console with Microphone Electrical Cabling Plastic Tubing Assembly Stereo Interface Box Alarm System (Rubber Squeeze Bulb)
Mode of Operation	Continuous	Continuous	Continuous
Computer-Based	No	No	No
Single Use	The system is reusable	The system is reusable	The system is reusable
Mode of Patient contact	Headset	Headset	Headset
Anatomical Contact Sites	Head	Head	Head
System Accuracy	N/A	N/A	N/A
Compatibility with MRI system	Yes	Yes	Yes

INDICATIONS FOR USE

510(k) Number

K121239

Device Name

MRI Multi-Channel Optical Communication System (MOC)

Indications for Use:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.

Prescription Use ☒

(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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