December 21, 2017

Ives EGG Solutions
John Ives
Design Engineer
25 Storey Avenue, #118
Newburyport, Massachusetts 01950

Re: K171102
Trade/Device Name: Ives MR Conditional Cup Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: Not Dated
Received: November 29, 2017

Dear John Ives:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171102

Device Name
Ives MR Conditional Cup Electrode

Indications for Use *(Describe)*
The Ives MR Conditional Cup Electrodes are intended for use in the general recording and monitoring of the electroencephalography (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording.

The Cup Electrodes are intended to be left in place during MR imaging at 1.5T and 3T as well as during CT scanning.

The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and MUST remain disconnected throughout the entire MR scan. EEG or EP should not be recorded throughout the entire the CT and MR imaging.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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010_510(k) Summary

Ives MR Conditional Cup Electrode (K171102)

Company Name:	Ives EEG Solutions, Inc.
Contact:	Mr. John Ives
Phone:	978-358-8006
Fax:	978-358-7825
Email:	johnrives@gmail.com

Summary Date:	December 8, 2017
Trade Name:	Ives MR Conditional Cup Electrode
Model Number:	CPE (Conductive Plastic Electrode)
Common Name:	Surface Electrode, Cutaneous electrode
Classification Name:	21 CFR 882.1350, Cutaneous Electrode GXY

Main Predicate Device:	510(k) Number:	K071118
	Manufacture:	Ives EEG Solutions, LLC
	Trade Name:	EEG Surface Electrode System
	Product Code:	GXY
Other Predicate Devices:	510(k) Number:	K130287
	Manufacture:	Rythmlink International, LLC Trade
	Name:	MR Conditional Cup Electrode, MR Conditional Webb Electrode
	Product Code:	GXY
Other Predicate Devices:	510(k) Number:	K122376
	Manufacture:	TruScan® Surface Electrodes
	Name:	TruScan® Surface Electrodes
	Product Code:	GXY

Description of Electrodes:
The cutaneous surface electrode (CPE) are electrodes that are all applied to the surface of the patient's skin, they are non-invasive. These electrodes are used for the recording of electroencephalography (EEG), evoked potential (EP) as well as the ground and reference associated with the recording. They consist of a disc or cup made from a variety of materials, which include, conductive plastic and Ag-Ag/Cl, materials that have long been used for this intended purpose throughout the industry and compatible to the MR environment. The conductive cup electrode is permanently connected to a PVC insulated copper lead wire varying in length from 6" to 9". This joint is then covered in a heat-shrink tube to provide a strain relief. The lead wires are staggered in length (6" to 9") and terminate in a small mass connector that conforms to DIN 42-802 for electrical safety. A blue sponge is provided to locate the lead wire termination off of the scalp and

at the top of the patient's head. To permit EEG monitoring, this small mass connector mates with a harness system as per K062880 (an Ives EEG Solutions 510K describing a Subdermal Wire Electrode System) which connects to the EEG recording instrument using molded "touch-proof" connectors which also conform to DIN 42-802. The Harness is disconnected for imaging. The electrode lead length is as short as possible to connect directly with the 10-20 EEG scalp site. This prevents coiling of the lead wires and as short as possible lead length to reduce or eliminate the RF heating antenna effect during MR scanning sequences. Electrode and lead materials are selected to avoid use of any magnetic ferrous metals.

Indications for Use

The Ives MR Conditional Cup Electrodes are intended for use in the general recording and monitoring of the electroencephalography (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording.

The Cup Electrodes are intended to be left in place during MR imaging at 1.5T and 3T as well as during CT scanning.

The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and MUST remain disconnected throughout the entire MR scan. EEG or EP should not be recorded throughout the entire the CT and MR imaging.

Substantial Equivalent to Predicate Devices

	Ives Surface EEG Electrodes Model: GCE SCE, SCE^S CPE^S	Rhythmlink International Model: Cup Electrode	TruScan ® Surface Electrodes
510K number	K171102	K130287	K122376

IFU	The Ives MR Conditional Cup Electrodes are intended for use in the general recording and monitoring of the electroencephalography (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording. The Cup Electrodes are intended to be left in place during MR imaging at 1.5T and 3T as well as during CT scanning. The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and MUST remain disconnected throughout the entire MR scan. EEG or EP should not be recorded throughout the entire the CT and MR imaging.	The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.	The PMT®f TruScan® Surface Electrodes are indicated for cutaneous use in the general recording and monitoring of the Electroencephalograph (EEG) and Evoked Potential (EP). The PMT® TruScan® Surface Electrodes are CT compatible and MR Conditional under the following conditions: * Static magnetic field strength of 1 .5-T only * Maximum spatial gradient magnetic field of 5,000 Gauss/cm (5OT/in) or less * The connector hub must be placed near the center MR system's bore, and must be at least 20-cm from the wall of the MR system's bore at all times. * The extension cable must be disconnected from the PMT TruScan Surface Electrode before scanning and MUST remain disconnected throughout the entire MR scan. * Normal Operating Mode of operation for the MR system with a maximum whole body averaged specific absorption rate (SAR) of 2.O-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
Classification Product Code	GXY	GXY	GXY
Indications For Use	Recording of the EEG, EP, GND, REF	Recording of the EEG, EP, GND, REF	Recording of the EEG, EP, GND,
Target Population	Adult	Adult	Adult
Age Range	>21	>21	>21

Length of Recording	temporary	temporary	temporary
Supervision	EEG Technologist	EEG Technologist	EEG Technologist
Size of electrode	1cm	1cm	1cm
Design	Cup electrode with hole for gel	Cup electrode with hole for gel	Cup electrode with hole for gel
Materials	ABS molded plastic with Ag- Ag/Cl	ABS molded plastic with Ag-Ag/Cl coating	Silver/silver chloride
Lead Design	Tinseled copper wire with silver coat with	Copper wire with Vinyl (PVC) insulation	Nichrome
Lead Length See below 1:	Tested at 6" to 11" as well as marketed	Tested at 3.9" but marketed at 9.5"	Tested and marketed at 9″
Performance	High quality EEG	High quality EEG	-
Biocompatibility	Long History	Long History	-
Mechanical Safety	Ideal	Ideal	-
Chemical Safety	OK	OK	-
Anatomical Sites	Surface, scalp, skin	Surface, scalp, skin	Surface, scalp, skin
Human Factors	Easily Placed by traditional means	Easily Placed by traditional means	Easily Placed by traditional means
Energy Used and/or Delivered	Record EEG Biopotential Only	Record EEG Biopotential Only	Record EEG Biopotential Only
Compatibility	Connects to any Standard Recording	Connects to any Standard Recording Device	Connects to any Standard Recording Device
Interconnection between electrode lead and	48" lead connects from EEG electrode to standard 1.5mm Safe-	48" lead connects from EEG electrode to standard 1.5mm Safe-Lead ("Touch-Proof")	48" lead connects from EEG electrode to standard 1.5mm
Connection during imaging	NO other connection to electrode set during	NO other connection to electrode set during imaging	
Where Used	Hospital, ICU, inpatient	Hospital, ICU, inpatient	
Packaging	Non-sterile in plastic bag	Non-sterile in plastic bag	Non-sterile, sealed in PE pouch
Electrical Safety	Connects with Safe-Lead	Connects with Safe-Lead	1.5mm Brass/Polypropylene IEC 60601-1 subclause 56.3(c) compliant
Static MRI field strength tested	1.5T and 3T	1.5T and 3T	1.5T only
Connector placement	Located at top of head using supplied sponge, thus near center of	Not specified	Must be at least 20cm from the wall of the MR bore at all times
Maximum SAR	3.2W/Kg	Not specified	2.0W/Kg

DIFFERENCE RATIONALE:

There are essentially no major differences between our device and the predicate device except as noted below.

1: There is a significant lead length difference between Rhythmlink as tested and Ives as tested (3.9" vs. 6"-11"); however, as marketed the difference is 9.5" vs. 6" to 11"). Testing showed that the leads connected to the subject device supported the safe and effective use of the device for the indications for use stated. Ives EEG Solutions found that the EEG technologist needs at least 6" to allow easy application of the electrode and also to allow for staggered lead lengths to extend from the 10-20 site to the connector at the top of the head, thus the longest lead is 11".

Non-Clinical Testing

Non-clinical testing has demonstrated that the Ives MR Conditional Cup Electrodes is MR Conditional and can safely remain on the patient during an MR scan under the following conditions:

- Static magnetic fields strength of 1.5 T and 3.0 T
- Maximum spatial gradient magnetic fields of 2,000 gauss/cm (20T/m) or less
- Transmit body and head coil, quadrature driven
- Maximum MR System reported whole-body averaged specific absorption rate (SAR) of 2 W/kg and whole-head averaged SAR of 3.2 W/kg
- The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and must remain disconnected throughout the entire MR scan.

Under the scan conditions defined above, the Ives MR Conditional Cup Electrodes is expected to produce a maximum temperature rise of less than 5ºC after 15 minutes of continuous scanning.

In clinical testing, the image artifact caused by the device extends approximately 3 mm from the Ives MR Conditional Cup Electrodes when imaged with a gradient echo pulse sequence in a 1.5 T and 3.0 T MRI system.

CONCLUSION:

Ives MR Conditional Cup electrodes are substantially equivalent to the predicate MRI Conditional EEG cutaneous electrode.