5. 510K Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information

Christine Vergely
Regulatory Affairs Manager
Neurovision Medical Products, Inc.
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Date of Summary:

Device Identification:

Trade or Proprietary Name:	*Paired Hydrogel Electrode (final name TBD)*
Common or Usual Name:	Hydrogel Surface Electrode
Classification Name:	Surgical nerve stimulator/locator
Device Class:	Class II
Classification:	§874.1820
Product Code:	ETN

Predicate Devices

The *Paired Hydrogel Electrodes* are substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- M203KEN; Neonatal ECG Electrode (K092744), referred to in this document as the Singlet Hydrogel (K092744)
- 3M Pediatric "Red Dot" hydrogel electrode accessory RLN Systems Nerve Locator/Monitor; Model A (K902080), superseded by,
- Neurovision (SE: Surface Electrode) Nerve Locator/Monitor (K954601)

Device Description

The *Paired Hydrogel Electrodes* are a modification of the M203KEN electrode currently distributed as the Singlet and Triplet Hydrogel Electrodes by Neurovision Medical Products. The Paired Hydrogel Electrode is created by attaching two Singlet M203KEN electrodes by their lead wires to the same DIN plug (shorting the electrodes). The Paired version is designed to provide a single pole of electrophysiological monitoring across a surface too wide to be covered by a single electrode.

Indication for Use

The Paired Hydrogel Electrode is used for evoked electrophysiological monitoring in soft tissue surgeries were motor nerves are at risk.

Technological Characteristics of Device in Relation to Predicate Devices

neurovision MEDICAL

Special 510k – Paired Hydrogel Electrode

510(k) number	Subject Device K042744	K954601	K092744	K902080
Brand Name	PAIRED HYDROGEL ELECTRODE	NERVE LOCATOR/MONITOR SYSTEM, MODIFICATION	NEONATAL ECG ELECTRODES	RED DOT 2269 INFANT MONITORING ELECTRODE
Description	Surface Electrode for EMG Monitoring	Neurovision SE (surface electrode) Nerve/Locator Monitor	Neonatal ECG Electrode, M203KEN	Neonatal ECG Monitoring Electrode
Indications for Use	The Paired Hydrogel Electrode is used for evoked electrophysiological monitoring in soft tissue surgeries were motor nerves are at risk.	The Neurovision SE is an electronic device consisting of a surgical nerve stimulator and an evoked EMG monitor with integrated detecting or warning capability. This device is intended for use in surgical procedures where motor nerves are at risk to assist the surgeon in locating these nerves.	Neonatal EGG Electrodes are intended for use in pediatric or neonatal electrocardiographic procedures where resting EGG monitoring is deemed necessary and is ordered by a physician. Such procedures include, in particular, patient EGG surveillance and EGG diagnosis recording. The Neonatal EGG Electrodes are applied to the surface of the body, single use only, and disposable. Neonatal ECU electrodes should be changed every 24 hours.	Neonatal ECG Monitoring
Product Code	ETN	ETN	DRX	DRX
Materials and Design	2 Comfort Gel A discs conjoined at DIN plug	Uses FDA approved surface electrodes	1 Comfort Gel A disc terminated at DIN plug.	FDA approved pediatric ECG/EMG/EKG hydrogel electrode
Bio-compatibility	Tested free of Sensitization, Cytotoxicity and Irriation	Per approved electrodes	Tested free of Sensitization, Cytotoxicity and Irriation	FDA approved
Compatible devices	EMG units	EMG units	EMG units	ECG, EKG, EMG units

Shelf-Life	3 years	N/A	3 years	N/A
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Attachment to Stimulator	DIN connector	DIN connector	DIN connector	Snap lead wire

Performance Testing

Performance testing of the electrode adhesion, impedance, and electrophysiological properties demonstrated equivalence between the paired hydrogel electrode and the predicate singlet.

Animal testing demonstrated the Biocompatibility of the materials and was conducted according to ISO 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization. Cytoxicity testing was according to the Agarose Overlay Method.

Shelf life testing was according to ANSI/AAMI EC12:2000 : Disposable ECG Electrodes and demonstrated a 3 year shelf life.

(End of 510(k) Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurovision Medical Products, Inc.
c/o Ms. Christine Vergély
Regulatory Affairs Manager
2225 Sperry Ave., Suite 1000
Ventura, CA 93003

APR - 8 2011

Re: K110138
Trade/Device Name: Paired Hydrogel Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: March 14, 2011
Received: March 16, 2011

Dear Ms. Vergély:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

4. Indications for Use:

Device Name: Paired Hydrogel Electrode

The Paired Hydrogel Electrode is used for evoked electrophysiological monitoring in soft tissue surgeries were motor nerves are at risk.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110138