K091163

510(K) Summary

Section 05 | 510(K) notification | Cutaneous Electrodes

Submitter Information

JUL 22 2009

FIAB SpA
Via P. Costoli, 4
50039 Vicchio
Florence - Italy

Phone: +39 055 84979216
Fax: +39 055 8497987
Contact person: Silvia Calabrò, Official Correspondent
Email: silvia@fiab.it

Device name and classification

Trade name:
PG471W, PG471/50W, PG474W, PG477W, PG479/32W, PG479/50W, PG479/75W FIAB disposable electrodes with cable for electro-stimulation.

Common name: cutaneous electrode.

Classification name: cutaneous electrode (21 CFR 882.1320, Product code GXY)

Predicate device

Lawfully marked device to which is claimed equivalence:

Trade Name	Manufacturer/Distributor	510(K) Number
Valuetrode	AXELGAARD MFG. CO. TD.	K970426

Device description

PG47xW SERIES are disposable adhesive electrodes with solid conductive gel. They consist of a conductive pad made of three primary layers: a non-woven fabric top, a carbon filled film and a solid hydrogel adhesive layer. Between the conductive film and the insulating top a 10 cm long cable is attached, terminated with 2 mm touch proof socket for the connection with electro-stimulating devices. Multiple shapes and sizes are available to accommodate placement on various location on the body. The electrodes are passive devices serving as interface between transcutaneous neurostimulation devices and the patient's skin. The electrodes are non-sterile and for single patient use only.

FIAB spa – Via P. Costoli, 4 – 50039 VICCHIO – FLORENCE – ITALY
☎ +39 0558497999 – 🖷 +39 0558497979 - www.fiab.it

Intended use

PG47xW SERIES cutaneous disposable electrodes with cable connection are intended for use with neurostimulation equipment designed for transmission of electric impulses to patient's skin.

Comparison to predicate

PG47xW SERIES electrodes have technological characteristics equivalent to those of the predicate devices (ValueTrode electrodes previously cleared under K970426), employing the same solid gel (the only patient contacting component) and having equivalent technological characteristics including comparable design, materials and equivalent packaging and labeling.

Although there are no guidance performance standards, as reported in Section 18, the electrodes are produced and tested according to all requirements laid down by the regulations in force so as to guarantee safety and effectiveness.
According to the risk-benefit analysis, the global residual risk has been deemed acceptable since it falls within the area between negligible risks and acceptable risks.

The devices have the same intended use as the predicate devices.
The performance is expected to be the same as predicate device.
See section 12 of the submission.

FIAB spa – Via P. Costoli, 4 – 50039 VICCHIO – FLORENCE – ITALY
☎ +39 0558497999 – 🖷 +39 0558497979 – www.fiab.it

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FIAB SpA
c/o Alberto Calabro
Via Costoli, 4, Viccio
Firenze,
Italy 50039

JUL 22 2009

Re: K091163
Trade/Device Name: FIAB disposable electrodes models PG471W, PG471/50W, PG474W, PG477W. PG479/32W, PG479/50W, PG479/75W
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: May 26, 2009
Received: June 9, 2009

Dear Mr. Calabro:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 Statement

Section 04 | 510(K) notification | Cutaneous Electrodes

Indications for Use

510(K) Number (if known): - K091163

Device Name:

FIAB disposable coutaneos electrodes, models:
PG471W
PG471/50W
PG474W
PG477W
PG479/32W
PG479/50W
PG479/75W

Indications For Use:

PG47xW SERIES cutaneous disposable electrodes with cable connection are intended for use with neurostimulation equipment designed for transmission of electric impulses to patient's skin.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

04/17/2009 **510(k) Number** K091163 1/1

FIAB spa – Via P. Costoli, 4 – 50039 VICCHIO – FLORENCE – ITALY
☎ +39 0558497999 – 🖷 +39 0558497979 – www.fiab.it