APR 26 2005

K050194

11. Summary of Safety and Effectiveness

Company Name: Axon Systems, Inc.
400-2200 Oser Ave
Hauppauge, NY 11788

Contact: Howard Bailin
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Summary Date January 17, 2005

Proprietary Name: Subdermal Needle Electrodes
Twisted Pair Needle Electrodes
Corkscrew (spiral) Needle Electrode

Common Name: Subdermal Needle Electrodes

Classification:

Class II	(Performance Standards)	
Number:	882.1350	Needle Electrode
Procodes:	GXZ	

Predicate Devices

Manufacturer: Nicolet Biomedical
Trade Name: Sterile Subdermal Needle Electrodes
FDA number: K010019

Manufacturer: TechnoMed Europe
Trade Name: Various Needle Electrodes
FDA number: K990015

Manufacturer: Agram Export-Import Company
Trade Name: Spiral Electrode
FDA number: K934779

Device Description
Axon Systems' Subdermal Needle Electrodes are disposable (for "Single Use Only"), sterile devices used to detect electro-physiological signals or provide electrical stimulation subcutaneously.

The electrodes are the interface medium between the diagnostic or monitoring equipment and the patient. The subdermal needle electrode is comprised of a small gauge stainless steel needle on one end electrically connected to lead wire and a "touch-proof" safety connector on the other end. The needle is inserted subdermally by a licensed physician or technologist under the supervision of a physician. The safety connector is connected to recording or monitoring equipment.

The safety connector is an industry standard DIN 42802 protected, "touch proof" connector and cannot be connected to an AC outlet.

Electrodes are used in clinical electro-diagnostic studies or intraoperative monitoring which may include electroencephalography (EEG), electromyography (EMG) or evoked potentials recording and electrical stimulation.

Subdermal Needle Electrodes are invasive since they are positioned subcutaneously and are used under the supervision of a licensed physician.

Intended Use
Axon Systems' Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction.

Technological Characteristics
Axon Systems' Subdermal Needle Electrode consists of an insulated wire, of various lengths, electrically connected to a small gauge, stainless steel needle on one end, and a DIN 42802 "touch-proof" safety connector on the other end. The connector is specifically designed so that it cannot be plugged into AC power outlet. The electrode is supplied in a sterile pouch. Materials used are the same as in the predicate devices.

Conclusions
Axon Systems' Subdermal Needle Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised or evident.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2005

Mr. Howard Bailin
Vice President, Chief Operating Officer
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppauge, New York 11788

Re: K050194
Trade/Device Name: Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: II
Product Code: GXZ
Dated: April 1, 2005
Received: April 5, 2005

Dear Mr. Bailin:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number	K050194
Device Name	Subdermal Needle Electrodes
Indications for Use	Axon Systems' Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. .

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Cardiovascular Devices
K050194