K062996

510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Summary Date:	September 29, 2006
Submitter's Information:	Howard Bailin Vice President, C.O.O. Axon Systems, Inc. 400-2200 Oser Ave Hauppauge, NY 11788 P: 631 436 5112 F: 631 436 5141 hbailin@axonsystems.com
Trade Names:	Axon Systems Disposable Stimulator Probes
Common Name:	Stimulator Probes
Classification Name:	Stimulator, Nerve (21. CFR 874.1820) Needle Electrode (21. CFR 882.1350)
Classification:	Class II (Performance Standards) Panels: Ear, Nose and Throat; 874.1820 Neurology; 882.1350 Procodes: ETN, GXZ
Predicate Devices:	Technomed Europe – Disposable Probes (K050325) Xomed Surgical Products – Ball Tip Monopolar stimulating probe (K992869)

JAN 12 2007

Summary:

Description
Stimulator probes are used as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring. The probes are available in various monopolar and bipolar configurations according to the required application. The probes are supplied sterile and are for single use only.

The probes are connected to an electrical stimulator using a flexible lead wire(s) and a "touch-proof" safety connector(s) on the distal end. Monopolar electrodes require a separate stimulator return electrode

Stimulator probes are used by the surgeon to locate and identify motor nerves and spinal nerve roots and to assess nerve function. Bipolar probes may also be used to record nerve action potentials directly from the nerve.

The probes are designed with a plastic handle and stainless steel active electrode shaft insulated to the tip. The probe shaft may be bent to allow viewing access under a microscope.

Intended Use
To locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

Technological Characteristics
Axon Systems' Disposable Stimulator Probes consist of an insulated probe shaft of various lengths mounted to plastic handle. The probe shaft is electrically connected to a DIN 42802 "touch-proof" safety connector on the other end. The electrode is supplied in a sterile pouch. Materials used are the same as in the predicate devices.

Conclusions
Axon Systems' Disposable Stimulator Probes 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
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Axon Systems, Inc.
% Mr. Howard Bailin
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Hauppauge, New York 11788

JAN 12 2007

Re: K062996
Trade/Device Name: Disposable monopolar and bipolar stimulator probes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: II
Product Code: GXZ
Dated: November 29, 2006
Received: November 30, 2006

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

Sincerely yours,

for

Mark N. Melkerson
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 (if known): K062996

Device Name: Disposable monopolar and bipolar stimulator probes

Indications For Use: To locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062996