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K 990683

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary and saftey and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

SUBMITTER INFORMATION

Company Name:	Axon Instruments, Inc.
Company Address:	1101 Chess Drive Foster City, CA 94404
Company Phone:	(650) 571-9400
Company Fax:	(650) 571-9500
Contact Person:	Andrew Blatz, Ph.D. Regulatory Affairs Manager Product-Line Manager Neurosurgical Devices Axon Instruments, Inc.
Date Summary Prepared:	January 7, 1999

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Guideline System 3000 MP-1 Micropositioner
Classification Name:	Stereotaxic Instruments and Accessories

IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Radionics	Brown-Roberts-Wells Stereotaxic System	K811452	6/1/81
Radionics	Semi-Micro-Electrode Kit	Preamendment device	Not applicable

DEVICE DESCRIPTION

The MP-1 Micropositioner is a three-axis positioning device for precise manipulation of probes or electrodes in stereotactic neurosurgical procedures. The "x" and "y" axes are driven by simple micrometer screws, while the "z" or depth axis is driven by a motorized lead-screw arrangement. The positioner allows for the accurate placement of probes within the three dimensional stereotactic space once it has been mounted on a legally marketed stereotactic frame.

SUBSTANTIAL EQUIVALENCE

The Guideline System 3000 MP-1 Micropositioner is substantially equivalent to the predicate devices. The intended use, labeling, physical characteristics, and safety features of the Guideline System MP-1 Micropositioner and the predicate devices are very similar, differing only in details that have no bearing on safety and effectiveness. The technologies involved in both the predicate devices and the Guideline System 3000 MP-1 Micropositioner are all time-tested, standard approaches and are listed in the comparison charts provided in this 510(k) submission.

INTENDED USE

The Guideline System 3000 MP-1 Micropositioner is intended for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

TECHNOLOGICAL CHARACTERSTICS

A comparison of the technological characteristics of the MP-1 Micropositioner to the predicate and legally marketed devices is provided within this submission.

PERFORMANCE DATA

The Guideline System 3000 MP-1 Micropositioner has been demonstrated to perform as intended with accuracy and repeatability. In accordance with our development plan, the Guideline System MP-1 Micropositioner has been extensively tested in both bench test and animal test conditions. Prototype instruments meet or exceed all appropriate Feature and Engineering Specifications and tolerances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1999

James C. Makous, Ph.D.
Product Line Manager, Neurosurgical Devices
Axon Instruments, Inc.
1101 Chess Drive
Foster City, California 94404

Re: K990683
Trade Name: Axon MP-1 Micropositioner
Regulatory Class: II
Product Code: HAW
Dated: August 4, 1999
Received: August 5, 1999

Dear Dr. Makous:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990683

Device Name: MP-1 Micropositioner

Indications for Use:

The **indications for use** of the Guideline System 3000 MP-1 Micropositioner are for procedures where a precise placement of probes, such as those used for electrophysiological recording and stimulation, lesioning, or chronic stimulation within the nervous system is required.

(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 General Restorative Devices
510(k) Number K990683

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)