The following is a revised Summary of Safety and Effectiveness with requested items removed:

Summary of Safety and Effectiveness

Voluntary regulatory standards	
Industry:	Meets or exceeds American Electroencephalograph Society Intraoperative Monitoring guidelines for EEG and evoked response devices.
Electrical:	UL544, IEC 601-1, C22.2 No. 125

Additional patient protection & safety features

"Touch proof" female safety electrode connectors
Insulated ABS plastic patient enclosures
Optical & transformer isolation
Line isolation transformer
Built-in software & hardware start-up diagnostics
Software & hardware shutdown protection
Zero average DC electrical stimulation
Hi, medium & low average stimulation intensity limited
Peak stimulation intensity limited
Hi level electrical stimulator disconnected on fault
Preamplifier DC fault limited to safe current (30uA)

Comparison of Intended Use to Predicate Devices

Type of Monitoring	Equivalent Device	Predicate Devices		
	Axon Systems Epoch 2000	**Axon Systems Sentinel-4 DC# 900482A**	**Moberg Medical Neurotrac II DC# K914571**	**Nicolet Viking IV DC# K842956 DC# K950270**
Cerebral ischemia	Yes	Yes	Yes	Yes
Show changes in EEG due to neuroactive drugs	Yes	Yes	Yes	Yes
Long term coma	Yes	Yes	Yes	
Seizure tracking	Yes		Yes	
Electrocorticography	Yes		Yes	Yes
Somatosensory Evoked potentials	Yes	Yes	Yes	Yes
Motor evoked potentials	Yes			Yes
Auditory evoked potentials	Yes	Yes	Yes	Yes
Visual evoked potentials	Yes	Yes	Yes	Yes
EMG	Yes	Yes		Yes
Direct Nerve stimulation/EMG	Yes	Yes		Yes

Based upon the documentation stated above and the safety and effectiveness criteria of the design and development process, validated by testing and quality control procedures, we claim the device to be safe, effective and substantially equivalent to the predicate devices noted.

The Epoch 2000 is similar is concept and function to our original product, the Sentinel-4 EEG/EP Intraoperative Monitor (K900482A), a class II device. This instrument is also used to monitor brain function and neurological activity utilizing EEG and multiple modality evoked potential techniques. The additional features incorporated in this product are designed to meet the current and expanding demands of health care professionals for more effective ways to monitor the neurological status of their patients without compromising safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV 20 1997

Mr. Howard Bailin
Vice President, General Manager
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppauge, New York 11788

Re: K971819
Trade Name: Epoch 2000 Neurological Workstation
Regulatory Class: II (two)
Product Code: 84 GWF
Dated: September 9, 1997
Received: September 10, 1997

Dear Mr. Bailin:

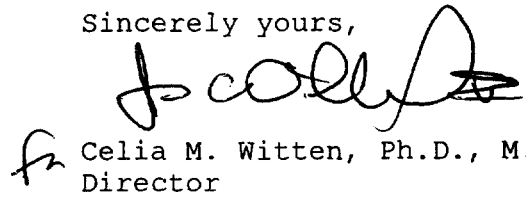
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,



for 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): K971819

Device Name: Epoch 2000 Neurological Workstation

Indications For Use: The Epoch 2000 is intended for use in the operating room and critical care areas for neurological monitoring and assessment. The instrument uses EEG, evoked potentials and EMG techniques to provide the health care professionals with information to help access a patient's neurological status during surgery or long-term monitoring in the ICU.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971819

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)