APR 2 3 2003

K030937

510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Brandon Epting, Regulatory Associate Phone: 610-378-0131, ext. 8498 Fax: 610-374-5360 Email: brandon.epting@arrowintl.com
Date summary prepared:	03/24/03
Device trade name:	StimuCath™ continuous nerve block set.
Device common name:	Peripheral nerve stimulating catheter and needle.
Device classification name:	CAZ, Class II, 21 CFR 868.5140, Anesthetic conduction kit.
Legally marketed devices to which the device is substantially equivalent:	- Arrow StimuCath™ continuous nerve block set (K021567). - HDC® Corporation CLA™ regional block needle (K994059).
Description of the device:	The StimuCath™ continuous nerve block device is an anesthesia conduction catheter that is electrically conductive. Using peripheral nerve stimulation, the user can locate specific nerves or nerve plexuses for continuous nerve block anesthesia or analgesia.
Intended use of the device:	The Arrow StimuCath™ continuous nerve block set permits placement for catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia. It is indicated for use up to 72 hours.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate devices.
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: - Flow rate - Leak test (positive pressure) - Holding strength of SnapLock™ adapter to catheter - Snap force of SnapLock™ - Biocompatibility tests - Power and current density calculations - Bond strength - Dielectric tests - Peel back tests
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2003

Mr. Brandon Epting
Regulatory Associate
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K030937
Trade/Device Name: StimuCath™ Continuous Nerve Block Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: March 24, 2003
Received: March 25, 2003

Dear Mr. Epting:

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030937

Device Name: StimuCath™ continuous nerve block set

Indications for Use: The Arrow StimuCath™ continuous nerve block set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K030937