Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 256 586 1580
Fax 256 586 8529

K041158

JUN 17 2004

Atrion Medical

11. 510(k) SUMMARY

Date of Preparation: April 30, 2003

Device Name: Atrion Epidural Anesthesia Kit with NeedleVISE™ sharps securing system

Common Name: Anesthesia Conduction Kit

Classification Name: Anesthetic Conduction Kit 21 CFR 868.5140, ProCode 73 CAZ
Accessory to single lumen hypodermic needle
21 CFR 880.5570, ProCode 80 FMI

Manufacturer: Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016

Contact: Mr. Dan Clark,
Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016
Telephone: (256) 586-1580, Fax: (256) 586-8529

Predicate: Cambridge Marketing, Inc. Needle Barn Stik Stopper® (K010038)
Devon Industries, Inc. Point-Lok® Needle Protection Device (K946289)
B. Braun Epidural Kit with Soft Tip Catheter (K971233)
Portex Continuous Epidural Anesthesia Tray (K802065)

Device Description:

The Atrion Epidural Anesthesia Kit with NeedleVISE™ Sharps Securing System consists of components necessary for conducting repeated administration of anesthetic agents in the epidural space. The kit also contains the NeedleVISE™ sharps securing system which is a multiple needle, single patient procedure use, disposable device used for securing the specialized needles found in sterile anesthesiology procedural trays.

As provided to the user, the NeedleVISE™ sharps securing system is retained in an upright position in the sterile procedure tray to allow for stability and one-hand insertion of sharps during a procedure. The healthcare professional using only one hand can render the sharps harmless while remaining with the patient in the sterile field. The purpose of the NeedleVISE™ sharps securing system is to provide a means to make engineered sharps control protection available within the sterile field, for all instances in which introduction of contaminated sharps containers is not acceptable.

Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 256 586 1580
Fax 256 586 8529

Atrion
Medical

Intended Use:

The Atrion Epidural Anesthesia Kit is intended for use in the administration of anesthetic agents into the epidural space. It is recommended that the epidural catheter be removed or replaced every 72 hours.

The NeedleVISE™ sharps securing system is intended for use in sterile anesthesiology procedure trays as a sharps securing device for the contaminated specialized needles that do not have integral engineered sharps safety devices.

Technological Characteristics:

All the components used in the Atrion Epidural Anesthesia Kit with NeedleVISE™ Sharps Securing System are legally marketed devices. The inclusion of these components in the kit will have the same implications as their current usage. The NeedleVISE™ sharps securing system has similar materials as the predicate products, but acts by locking the used sharp into a metal retaining clip contained within the plastic housing.

Summary of Testing:

As the only new component to the kit, testing was conducted on the NeedleVISE™ sharps securing system. The tests included mechanical property testing to assess impact, stability, puncture and leak resistance. The results showed the NeedleVISE™ device to be substantially equivalent to the predicate sharps securing devices. Clinical utility was evaluated in field trials designed to assess ease of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Mr. Dan Clark
Vice President Regulatory and Quality
Atrion Medical Products, Incorporated
1426 Curt Francis Road
Arab, Alabama 35016

Re: K041158
Atrion Epidural Anesthesia Kit with NeedleVISE™ sharps securing system
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: 73 CAZ
Dated: April 30, 2004
Received: May 3, 2004

Dear Mr. Clark:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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.

In addition, we have determined that your device kit contains Povidone Solution which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K041158

Device Name: Atrion Epidural Anesthesia Kit with Atrion NeedleVISE™ sharps securing system

Indications For Use:

The Atrion Epidural Anesthesia Kit is intended for use in the administration of anesthetic agents into the epidural space. It is recommended that the epidural catheter be removed or replace every 72 hours.

The NeedleVISE™ sharps securing system is intended for use in sterile anesthesiology procedure trays within the sterile field as a sharps securing device for the contaminated specialized needles that do not have integral engineered sharps safety devices.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lina M. Pinto

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

510(k) Number: K041158