K032981

APR 2 2 2004

Tim Duvall
President
Office Number (925) 820-3128

InVaMed Technologies, Inc.
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510(k) Summary – Dated September 19, 2003

General Information

Classification:	Class II
Trade Name:	SPpro™ - ESP
Submitter:	InVaMed Technologies, Inc. 9955 Titan Park Circle Littleton, CO 80125
Contact:	Tim Duvall President (925) 820-3128

Device Identification

A. Common Name

Epidural Needle with Sharps Injury Protection Feature
Spinal Needle with Sharps Injury Protection Feature

B. Classification Name

Needle, Conduction, Anesthetic (W/WO Introducer)

C. Regulation Number

858.5150

D. Panel

Anesthesiology

E. Product Code

BSP

F. Class

Class II

Predicate Devices

Manan Epidural Needle from Manan Medical Products, Inc. K980536
Manan Spinal Needles from Manan Medical Products, Inc. K983620
Perifix® Safety Epidural Needle from B. Braun Medical, Inc. K013610

Device Description Information

Intended Use

The SPpro™ ESP is an anesthesia conduction needle incorporating a needle tip shielding mechanism to aid in the prevention of needle-stick injuries after use to deliver an anesthetic and/or therapeutic agent to provide regional anesthesia. The needle can be used for a single dose administration or in conjunction with a catheter for continuous regional anesthesia.

Device Description

The SPpro™ ESP anesthesia conduction needle is a single use device for injection of local anesthetics into body cavities other than blood vessels. The device will be packaged as sterile single units or incorporated into kits. The device is designed with a tip shield and sheath mechanism integrated with the introducer hub to aid in the prevention of sharps injuries. After activation the shield covers the introducer tip. The device is disposed of according to institutional procedure in a sharps container.

Biocompatibility

Although the SPpro™ ESP sharps injury protection device has no direct contact with internal body fluids the materials and assembly methods were selected to provide for transient external tissue contact biocompatibility.

Biocompatibility testing on the therapeutic portion of the device included all tests performed on the predicate devices. The therapeutic devices are already approved devices made for InVaMed Technologies by Manan Medical Products, Inc.

Device Performance/Product Testing

Functional and simulated clinical testing was performed to support that there are no new issues or effectiveness raised by adding the sharps injury protection feature. The SPpro™ ESP met all functional requirements and specifications. Clinical simulation testing was in accordance with the Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA issued on December 31, 2002.

Technology Characteristics

The therapeutic device is equivalent technologically to the devices mentioned under predicate devices above. The therapeutic devices are already approved devices made for InVaMed Technologies by Manan Medical Products, Inc.

The safety feature, which has been integrated with the therapeutic portion of the device, is the reason for this submission. The safety feature is an active shielding system that that incorporates a second hub section integrated with the luer portion of the needle that slides up from the needle hub and locks over the needle tip. A second feature incorporates a plastic sheath attached to the sliding portion and the luer hub, which covers the previously exposed canula of the needle.

Substantial Equivalence

The InVaMed SPpro ESP needle incorporates an active needle tip cover mechanism to minimize needle stick injuries when used to access non-vascular areas of the body to administer local anesthetics. The basic design, methods of manufacturing, and materials used in the therapeutic portion of the device are substantially equivalent to the predicate devices, Manan Epidural Needle and Manan Spinal Needles from Manan Medical Products, Inc. While basic design, methods of manufacturing, and materials used in the safety portion of the device differ the technological equivalence exist between the predicate devices, Perifix® Safety Epidural Needle from B. Braun Medical, Inc. Our application for this device is substantially equivalent to the aforementioned devices already approved for use. The clinical indications for use remain unchanged. InVaMed believes the SPpro ESP anesthesia conduction needle is substantially equivalent to currently marketed anesthesia conduction needles and an anesthesia conduction needle with sharps injury protection features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Mr. Tim Duvall
President
InVaMed Technologies, Incorporated
9955 Titan Park Circle
Littleton, Colorado 80125

Re: K032981
Trade/Device Name: SPpro ESP, Models ESP 603-18-05 and ESP 603-18-09
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: March 16, 2004
Received: March 19, 2004

Dear Mr. Duvall:

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.

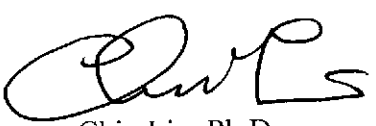
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

Indications for Use

510(k) Number (if known): **K032981**

Device Name: **SPpro ESP**

Indications For Use:

The SPpro™ ESP is an anesthesia conduction needle incorporating a needle tip shielding mechanism to aid in the prevention of needle-stick injuries after use to deliver an anesthetic and/or therapeutic agent to provide regional anesthesia. The needle can be used for a single dose administration or in conjunction with a catheter for continuous regional anesthesia.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

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