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Revised Pages 3-1 – 3-2, September 20, 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

IMD INC.
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(800)-824-8223, or (801) 745-4700

Contact:

Walter Zohmann, President
IMD INC.
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(800)-824-8223, or (801) 745-4700

Device Name:

TradeNames: IMD's Tuohy needle; Quincke needle; Pencil Point needle
Common Names: Anesthetic conduction needles, epidural/spinal needles

Classification Name: Anesthesia conduction needles (Reference 21 CFR 868.5150)

Product Class: Class II

Product Code: BSP

Preparation date of summary: January 22, 2007

Predicate Devices:

2.1 Busse Hospital Disposables, Inc. Specialty Needles (Spinal Needle, Pencil Point …), K061394, 09/06/2006;
2.2 Pajunk GMBH's Tuohy Needles, Quincke Needles, … , K040965, 09/07/2004;
2.3 IMD's Anesthetic Needle (Gertie Marx), K931644, 09/22/1993.

Device Description:

Anesthesia conduction needles consist of a luer hub, a stainless steel cannula with various tip types, and a stainless steel stylet. These needles are provided as sterile, single use, disposable devices. They may be packaged individually or included in regional anesthesia trays (kits). Anesthesia conduction needles fit into an introducer needle. This is a simple hypodermic needle to make the initial puncture through the skin to aid in the placement of the anesthesia conduction needle. The later can facilitate the placement of an epidural catheter for continuous infusion of local anesthetics into the epidural space for longer pain relief.

The IMD anesthesia conduction needles – Tuohy, Quincke, and Pencil Point – are single use, sterile and latex-free medical devices for transient delivery of anesthetics during regional anesthesia. The cannula is stabilized during puncture with use of an inner stylet. This stylet is withdrawn after the anesthesia conduction needle has reached its anatomical site for regional anesthesia. Then the anesthetics can be applied transiently (i.e., within minutes) by the professional anesthetist. Alternatively or additionally, an epidural catheter may be placed through the anesthesia conduction needle. The needle is withdrawn and the epidural catheter tip may remain in the epidural space for pain treatment.

Intended Use:

IMD's specialty / anesthesia needles – Tuohy, Quincke and Pencil Point Needles – are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Technology Characteristics:

The IMD anesthesia conduction needles – Tuohy, Quincke, and Pencil Point – have the same technological characteristics as the predicate devices identified above. The IMD anesthesia conduction needles – Tuohy, Quincke, and Pencil Point – are equivalent in design physical dimensions, luer hub, metal and plastics materials, and packaging to the IMD anethesia needle (Gertie Marx)® cleared under 510(k) number K931644. They differ only in tip configurations.

Biocompatibility and sterilization are equivalent to to the IMD anethesia needle Gertie Marx)® cleared under 510(k) number K931644, since the materials, packaging, and sterilzation processes are the same.

Conclusion:

The majority of anesthesia conduction needles are pre-amendment devices, due to the fact that they have been available to anesthesiologists for about 100 years. These devices have a long history of safe use in the clinical environment. The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Walter Zohmann
President
International Medical Development, Incorporated
9202 Kelley Drive
Post Office Box 510
Huntsville, Utah 84317

OCT 5 ~ 2007

Re: K070354
Trade/Device Name: IMD's Anesthesia Needles (Tuohy, Quincke, and Pencil Point)
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: September 20, 2007
Received: September 25, 2007

Dear Mr. Zohmann:

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.

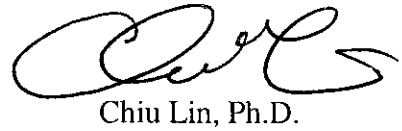
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K070354

Device Name: IMD's Anesthesia Needles (Tuohy, Quincke, and Pencil Point)

Indications For Use:

IMD's specialty / anesthesia needles – Tuohy, Quincke and Pencil Point Needles – are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

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

510(k) Number: K070354