K113662

SUMMARY OF SAFETY AND EFFECTIVENESS

APR 2 0 2012

SUBMITTED BY: IMD INC.
560 Hwy 39 P O Box 510
Huntsville UT 84317
(800)-824-8223, or (801) 745-4700

01. DEVICE NAME (Trade/common, and classification): IMD's Fenestrated Peripheral Nerve Block Needle;

Product Code: CAZ (BSP, MEB)

Regulation Nos.: 868.5140 (868.5150, 880.5725)

02. PREDICATE DEVICES:

- MPS Acacia Nerve Block Needle, K052946, cleared 12/08/2005;
- Life-Tech's Peripheral Nerve Block Support Tray, K073187, cleared 04/22/2008.

See also the FDA's 510(k) database of several other products under the same or similar classification (BSP, 868.5150; MEB, 880.5725), also found SE, or pre-ammendment.

- IMD's Anesthetic Needles (Touhy, Quincke and Pencil Point), K070354, cleared 10/05/2007; identical materials, manufacturers, sterilizers as IMD's Fenestrated Needle;
- IMD's Anesthetic Needle (Gertie Marx), K931644, 09/22/1993; also identical materials, manufacturers, sterilizers;
- B. Braun Nerve Block Catheter, K030830, 07/15/2003; fenestrations;
- I-Flow Corp's Intraop Catheter, K991543, 10/25/1999; fenestrations.

03. DESCRIPTION: The IMD Inc. Fenestrated Nerve Block Needle shares major similarities with the predicate device(s), inasmuch as the configuration, materials, use, labeling and safety issues remain basically unchanged to the IMD predicates. It consists of a plastic hub, and a stainless steel cannula. It has the same pencil point and same side outlet (only more). The addition of fenestrations is similar to predicate anesthesia catheters.

The IMD New Fenestrated Peripheral Nerve Block Needle is an anesthetic needle for peripheral nerve blocks using a local anesthetic solution. The distinct advantage offered by IMD's Fenestrated Peripheral Nerve Block Needle is due to the fenestrations. These eliminate the critical locating of the desired nerve to be blocked and only require that the needle be located in the general area for effective use.

04. INDICATIONS FOR USE / INTENDED USE:

IMD's New Fenestrated Peripheral Nerve Block Needle is a single patient use peripheral

nerve block needle with injection capabilities. It can be used to provide local or regional nerve blocking by the injecting of a local anesthetic.

It is to be used only under the direction of a licensed clinician.

05. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The IMD's Fenestrated Peripheral Nerve Block Needle shares the identical characteristics, features, materials, methods of manufacture / manufacturer, packaging / packager, and sterilization / sterilizer as two of the predicate needles. It's intended use is identical to other predicate needles / catheters. It is therefore SE to the predicate devices listed above. In addition:

    - No record of unexpected patient problems or adverse reactions were found in our review of the FDA's MAUDE, Safety Alert, and MDR databases;

    - The device and its packaging are tested by an independent lab for sterility, with validated sterilization, and will be subjected to inspection / testing by IQC, in-process QC, and finished goods QC, and monitored in the field by means of our CAPA system.

06. SAFETY AND EFFECTIVENESS: There are no substantive differences between the device defined in this 510(k) submission and the predicate devices. It is similar to the material and manufacturing / sterilization technologies that are currently used in other similar medical devices, and identical in these areas to the IMD predicates. It was developed and documented under IMD's Quality Management System, under the Quality System Regulation, 21 CFR Part 820, including design / change control, and is verified / validated to applicable standards / guidance documents, including vendors' and our SOPs. It is designed and manufactured to be safe and effective when used as intended, under a licensed clinician's supervision. Its safety and effectiveness was further tested clinically under IDE G040058 and appropriate IRBs.

07. IMD's Fenestrated Peripheral Nerve Block Needle share similar indications for use, and characteristics and functional features, and thus are substantially equivalent to the currently marketed predicate devices, cited above.

Signed: Walter Zohmann Dated: 3-16-2012

Walter Zohmann President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Walter Zohmann
President
International Medical Development Inc. (IMD)
560 Highway 39
P.O. Box 510
Huntsville, Utah 84317

APR 20 2012

Re: K113662
Trade/Device Name: Fenestrated Nerve Block Needle
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: March 16, 2012
Received: March 27, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 Form (Text Version)

Indications for Use

510(k) Number (if known): K113662

Device Name: Fenestrated Nerve Block Needle

Indications for Use:

IMD's New Fenestrated Nerve Block Needle is a single patient use needle to provide local or regional nerve blocking by the injecting of a local anesthesia.

It is to be used only under the direction of a licensed clinician.

Prescription Use X (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 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: K113662