K070801

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MAY 24 2007

Pre-market Notification for IMM Hypodermic Needle Set

IMM Hypodermic Needle Set

510(k) Summary of Safety and Effectiveness

1. Submitter's Name:

INNOVATIVE MEDICAL MAUFACTURING COMPANY
107, 181 Lane, Sect. 1 Yong Jane Road
Chunan, Miaoli, 350 TAIWAN (ROC)

Contact: J. P. Lee, General Manager

2. Name of Device

Common/Usual Name:	Hypodermic Needle Set
Proprietary Name:	IMM™ Hypodermic Needle Set
Classification Name:	Needle, hypodermic, single lumen

3. Predicate Device

Trade Name	510(k) Number	Decision Date
Nipro Scalp Vein Set	K955053	01/04/1996
SURFLO Winged Infusion Set	K771204	07/14/1977

4. Device Description

The IMM™ Hypodermic Needle Set consists of a conventional stainless steel needle, needle hub, extension tubing, clamp, and standard female 6% luer conical fitting for connection to a device contains a male luer fitting.

5. Indication for Use

The IMM™ Hypodermic Needle Set is to be used for sampling blood from or infusing fluid into body system underneath the skin.

6. Technological Characteristics

The IMM™ Hypodermic Needle Set has a conventional stainless steel needle, needle hub, extension tubing, clamp, female luer fitting with an end cap. The end cap can be removed to allow for connection of the female luer fitting to a device contains a male luer fitting for sampling or administering fluid.

7. Performance Summary

The functional and performance tests demonstrated that the IMM™ Hypodermic Needle Set meets specific requirements established in voluntary standards: ISO 594, and ISO 7864. Biocompatibility tests indicated that the device meets the requirements per ISO 10993 for "limited exposure, indirect blood path, external communicating device".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innovative Medical Manufacturing Company
C/O Mr. Joseph J. Chang, PhD, P.E.
Innomedtech LLC
7128 Staffordshire Street
Houston, Texas 77030

MAY 24 2007

Re: K070801
Trade/Device Name: IMM™ Hypodermic Needle Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 16, 2007
Received: March 23, 2007

Dear Dr. Chang:

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.

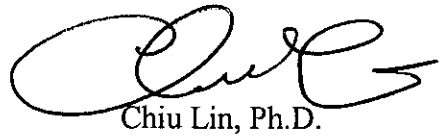
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K070801

510(k) Number (if known): K070801

Device Name:
IMM™ Hypodermic Needle Set

Indications For Use:
The IMM™ Hypodermic Needle Set is to be used for sampling blood from or infusing fluid into body system underneath the skin.

Prescription Use X 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

510(k) Number K070801