JAN 14 2011

K102584

8. 510(K) SUMMARY

Proprietary Name:	IMC Hypodermic Needle
Common Name:	HypodermicNeedle
Classification Name:	Hypodermic Single Lumen Needle (21 CFR 880.5570)
Device Clarification:	Class II
Panel Code:	80
Product Code:	FMI
Submitter Information:	International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173
Summary Prepared By:	Peter Kim Director of Quality Assurance International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173 Telephone: 847-619-9926 Fax: 847-619-9927 e-mail: peterkim@intlmedsurg.com
Date Prepared:	January 4, 2010
Predicate Devices:	• Nipro Medical Corporation (K052474)

Device Name(s):

IMC Hypodermic Needle (non-sterile and sterile)

Classification Panel:

General Hospital

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

International Medsurg Connections, Inc is claiming substantial equivalence of the IMC Hypodermic Needle with the currently marketed:

Description	510(k) Number
Nipro Hypodermic Needle	K052474

Device Description

This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

This device is consist of hub, cannula and protector and has difference hub color per each of gauges.

Statement of Intended Use

Indications For Use: This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

Name/Description

Description	Size	Sterility
16 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
17 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
18 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
19 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
20 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
21 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
22 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
23 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
24 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
25 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
26 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
27 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
28 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
29 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile
30 Gauge Hypodermic needle	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	Sterile & Non-sterile

New Devices as Compared to Marketed Device(s)

The IMC Hypodermic needle and the predicate device (Nipro Hypodermic needle) are intended to be used to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

Feature/ Characteristic	IMC Hypodermic Needle	Nipro Hypodermic Needle: K052474 (Predicate)
Intended Use	is device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin	ipro Hypodermic Needles are intended for use to inject fluids into or withdraw fluids from the parts of the body
Material		
Hub of Needle	Polypropylene (PP)	Polypropylene (PP)
Protector	Polypropylene (PP)	Polypropylene (PP)

Feature/ Characteristic	IMC Hypodermic Needle	Nipro Hypodermic Needle: K052474 (Predicate)
Cannula	SUS 304	SUS 304
Adhesive	Epoxy Resin	Epoxy Resin
colors		
16G	White color	White color
17G	Red-violet color	Mauve color
18G	Pink color	Pink color
19G	Cream color	Cream color
20G	Yellow color	Yellow color
21G	Deep green color	Green color
22G	Black color	Black color
23G	Deep Blue color	Blue color
24G	Medium purple color	Purple color
25G	Orange color	Orange color
26G	Brown color	Brown color
27G	Medium gray color	Gray color
28G	Blue-green color	Blue-green color
29G	Red color	Red color
30G	Yellow color	Yellow color
Length	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"	½", 5/8", ¾", 7/8", 1", 1 ¼" and 1 ½"
Gauge	16G, 17G, 18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G & 30G	16G, 17G, 18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G & 30G
Cover dimension	½" size: 40mm 5/8" size: 40mm ¾" size: 40mm 7/8" size: 40mm 1" size: 40mm 1 ¼" size: 56mm 1 ½" size: 56mm All gauges have the same dimension.	½" size: 42mm 5/8" size: 42mm ¾" size: 42mm 7/8" size: 42mm 1" size: 42mm 1 ¼" size: 55mm 1 ½" size: 55mm
Cover color	Clear (for all gauges)	Clear (for all gauges)
Tip configuration	Bevel	Bevel

Performance Data:

Performance Characteristics	Test Method	Acceptance Criteria	IMC Hypodermic Needle	Nipro Hypodermic Needle K052474
Hub/needle bond strength	ISO 7894 :1993	16G-19G : >69N 20G : >54N 21G: >44N 22G: >40N 23G-24G: >34N 25G-30G: >22N	Meets Standard Criteria	Meets Standard Criteria

Conclusions:

The indications for use, technology, specification, safety of the IMC Hypodermic needle and the predicate devices K052474 are essentially the same. The differences between the hypodermic needle are minor and do not raise new issues of safety or effectiveness. Hence, the IMC Hypodermic needles are substantially equivalent to the predicate device.

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. Peter Kim
Director of Quality Assurance
International Medsurg Connection
935 North Plum Grove Road, Suite F
Schaumburg, Illinois 60173

JAN 14 2011

Re: K102584
Trade/Device Name: IMC Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 10, 2010
Received: December 20, 2010

Dear Mr. Kim:

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.

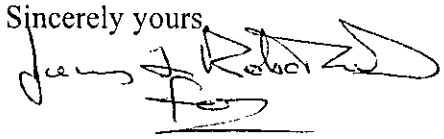
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

K102584

510(k) Number :

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) Acting for Richard Chapman
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102584