AUG 18 2011 K110882

8. 510(K) SUMMARY

Proprietary Name:	IMC Insulin Syringe
Common Name:	Insulin Syringe
Classification Name:	Piston Syringe (21 CFR 880.5860)
Device Clarification:	Class II
Panel Code:	80
Product Code:	FMF
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:	March 14, 2011
Predicate Devices:	• Becton Dickinson Consumer Healthcare (BD) - K024112

Device Name(s):

IMC Insulin Syringe (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 Insulin Syringe with the currently marketed:

Description	510(k) Number
BD Insulin Syringe	K024112

Device Description

This device is intended for the subcutaneous injection of insulins

This device is consisting of barrel, plunger, piston, cannula (which is fixed in the barrel nozzle lumen), top cap and cannula cap (orange color) with different gauges and cannula length.

Statement of Intended Use

Indications For Use: This device is intended for the subcutaneous injection of insulins

Name/Description

Category	Description	Sterility
Insulin Syringe	0.3cc Insulin Syringe with 28G x ½"	Sterile & Non-sterile
	0.3cc Insulin Syringe with 29G x ½"	Sterile & Non-sterile
	0.3cc Insulin Syringe with 30G x ½"	Sterile & Non-sterile
	0.3cc Insulin Syringe with 30G x 5/16"	Sterile & Non-sterile
	0.3cc Insulin Syringe with 31G x 5/16"	Sterile & Non-sterile
	0.5cc Insulin Syringe with 28G x ½"	Sterile & Non-sterile
	0.5cc Insulin Syringe with 29G x ½"	Sterile & Non-sterile
	0.5cc Insulin Syringe with 30G x ½"	Sterile & Non-sterile
	0.5cc Insulin Syringe with 30G x 5/16"	Sterile & Non-sterile
	0.5cc Insulin Syringe with 31G x 5/16"	Sterile & Non-sterile
	1cc Insulin Syringe with 28G x ½"	Sterile & Non-sterile
	1cc Insulin Syringe with 29G x ½"	Sterile & Non-sterile
	1cc Insulin Syringe with 30G x ½"	Sterile & Non-sterile
	1cc Insulin Syringe with 30G x 5/16"	Sterile & Non-sterile
	1cc Insulin Syringe with 31G x 5/16"	Sterile & Non-sterile

New Devices as Compared to Marketed Device(s)

The IMC Insulin Syringe and the predicate device (BD Insulin Syringe) are intended for the subcutaneous injection of insulins

Feature/Characteristic	IMC Insulin Syringe	BD Insulin Syringe: K024112 (Predicate)
Intended Use	This device is intended for the subcutaneous injection of insulins	BD Insulin Syringes is intended for the subcutaneous injection of insulins
Material		
Barrel	Polypropylene (PP)	Similar
Piston	PolyIsoprene	Similar
Plunger	High Density Polyethylene (HDPE)	Similar
Cannula (or Needle)	SUS 304	Similar
Cannula cap (or Needle cap)	High Density Polyethylene (HDPE)	Similar

Feature/Characteristic	IMC Insulin Syringe	BD Insulin Syringe: K024112 (Predicate)
Top cap	High Density Polyethylene (HDPE)	Similar
Lubricant	Silicone	Similar
Length	5/16" (8mm) and ½" (12.7mm)	5/16" (8mm) and ½" (12.7mm)
Gauge	28G, 29G, 30G and 31G	30G and 31G
Needle Cover Length	5/16" size: 21.5mm ½" size: 25.5mm All gauges have the same dimension.	5/16" size: 21.5mm ½" size: 25.5mm All gauges have the same dimension.
Cover color	Orange (for all gauges)	Orange(for all gauges)
Tip configuration	Bevel	Bevel
Size	1cc , 0.5cc & 0.3cc	1cc , 0.5cc & 0.3cc

Performance Data:

Performance Characteristics	Test Method	Acceptance Criteria	IMC Insulin Syringe	BD Insulin Syringe K024112
Hub/needle bond strength	ISO 7894 :1993	25G-30G: >22N	Meets Standard Criteria	Meets Standard Criteria
Graduation	ISO 8537:1991(E)	A- Volumes less than half the nominal capacity : +/-(1.5% of the nominal capacity +2% of the expelled volume) B - Volumes equal to or greater than half the nominal capacity : +/-(5% of the expelled volume)	Meets Standard Criteria	Meets Standard Criteria

Conclusions:

The indications for use, technology, specification, safety of the IMC Insulin Syringe and the predicate device K024112 is essentially the same. The differences between the Insulin Syringe are minor and do not raise new issues of safety or effectiveness. Hence, the IMC Insulin Syringes 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

International Medsurg Connection
C/O Peter Kim
Director of Quality Assurance
935 N Plum Grove Road, Suite F
Schaumburg, Illinois 60173

AUG 18 2011

Re: K110882
Trade/Device Name: IMC Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 3, 2011
Received: August 8, 2011

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

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

510(k) Number :

Device Name: IMC Insulin Syringe

Indications For Use: This device is intended for the subcutaneous injection of insulins.

Name/Description

Size	Gauge	Size	Sterility
0.3cc	28G	½" (12.7mm)	Sterile & Non-sterile
	29G	½" (12.7mm)	Sterile & Non-sterile
	30G	½" (12.7mm) & 5/16" (8mm)	Sterile & Non-sterile
	31G	5/16" (8mm)	Sterile & Non-sterile
0.5cc	28G	½" (12.7mm)	Sterile & Non-sterile
	29G	½" (12.7mm)	Sterile & Non-sterile
	30G	½" (12.7mm) & 5/16" (8mm)	Sterile & Non-sterile
	31G	5/16" (8mm)	Sterile & Non-sterile
1cc	28G	½" (12.7mm)	Sterile & Non-sterile
	29G	½" (12.7mm)	Sterile & Non-sterile
	30G	½" (12.7mm) & 5/16" (8mm)	Sterile & Non-sterile
	31G	5/16" (8mm)	Sterile & Non-sterile

Prescription Use ___ ____ AND/OR Over-The-Counter Use ___X ____
(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)

8/18/11

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

510(k) Number: K110882