DEC 2 0 2010

K102969

8.0 510(K) SUMMARY

Trade Name:	IMC Piston Syringe
Common Name:	Piston Syringe
Classification Name:	Piston Syringe (21 CFR subpart E §880.5860 and §880.5570)
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:	September 24, 2010
Predicate Devices:	• IMC piston syringe (K022159)

Device Name(s):

IMC Piston Syringe

Classification Panel:

General and Plastic Surgery

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

International Medsurg Connections, Inc is claiming substantial equivalence of the new piston syringe with the currently marketed:

Description	510(k) Number	Clearance Date
IMC piston syringe	K022159	11/7/2002

Device Description

The device consists of a calibrated hollow barrel and a movable plunger with piston. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into or withdraw fluids from, the body.

Statement of Intended Use

This device is intended for the injection of fluids into, or withdraws of fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe consisting of a calibrated hollow barrel and a movable plunger. This submission includes drapes that will be sold both sterile and non-sterile.

This submission includes piston syringe that will be sold both sterile and non-sterile. Non-sterile syringes are to be sold to OEMs for EtO sterilization according to their validated process per ANSI/AMMI/ISO 11135. Sterile syringes are to be sold directly to users after EO sterilization validation per ANSI/AMMI/ISO 11135

Category	Device Name	Sterility
Piston syringe	Syringe 1cc Luer Slip	Sterile and Non-sterile
	Syringe 2cc Luer Lock	Sterile and Non-sterile
	Syringe 2cc Luer Slip	Sterile and Non-sterile
	Syringe 3cc Luer lock	Sterile and Non-sterile
	Syringe 3cc Luer Slip	Sterile and Non-sterile
	Syringe 5cc Luer lock	Sterile and Non-sterile
	Syringe 5cc Luer Slip	Sterile and Non-sterile
	Syringe 10cc Luer lock	Sterile and Non-sterile
	Syringe 10cc Luer Slip	Sterile and Non-sterile
	Syringe 20cc Luer lock	Sterile and Non-sterile
	Syringe 20cc Luer Slip	Sterile and Non-sterile
	Syringe 30cc Luer lock	Sterile and Non-sterile
	Syringe 30cc Luer Slip	Sterile and Non-sterile
	Syringe 60cc Luer lock	Sterile and Non-sterile
	Syringe 60cc Luer Slip	Sterile and Non-sterile
	Syringe 100cc Luer lock	Sterile and Non-sterile
	Syringe 100cc Luer Slip	Sterile and Non-sterile

New Devices as Compared to Marketed Device(s)

The new piston syringe and the predicate device (IMC piston syringe – K022159) are used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The new piston syringe has the same intended use, the same technological characteristics and the same materials with exception of the piston material. Design differences are considered minor. The current piston material for IMC piston syringe is Santoprene but new piston syringe will use the alternative piston material (Isoprene) which is widely used in syringe manufacturing industry.

Feature/ Characteristic	New piston syringe (with Isoprene)	IMC piston syringe-K022159 (Predicate)
Material Composition		
Barrel	Polyethylene R370Y	Same
Piston	Isoprene	Santoprene
Plunger	Polyethylene R370Y	Same
Lubricant	High capability silicon oil	Same
Design Feature		
Design	See section 13	Similar
Dimension	See section 13	Similar
Volume	1cc, 2cc, 3cc, 5cc, 10cc, 20cc, 30cc, 60cc and 100cc	Similar

Performance Data:

Performance Characteristics	Test Method	New piston syringe (with Isoprene)	IMC piston syringe-K022159 (Predicate)
Test method for air leakage past syringe piston during aspiration, and for separation of piston and plunger	ISO 7886-1:Annex B	Meet the requirement	Same
Test method for liquid leakage at syringe piston under compression	ISO 7886-1:Annex D	Meet the requirement	Same

Conclusions:

The indications for use, technology, specification, safety of the piston syringe with Isoprene and the current IMC piston syringe (K022159) are essentially the same. The differences between the syringes are minor and do not raise new issues of safety or effectiveness. Hence, the piston syringe with Isoprene is substantially equivalent to the current IMC piston syringe.

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

DEC 20 2010

Re: K102969
Trade/Device Name: IMC Piston Syringes
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMF, FMI
Dated: November 2, 2010
Received: November 2, 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.

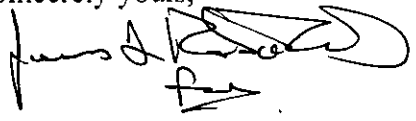
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

4.0 INTENDED USES / INDICATION:

International Medsurg Connection's piston syringe is intended for the injection of fluids into, or withdraw of fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe consisting of a calibrated hollow barrel and a movable plunger. The intended use is the same as the intended use on IMC piston syringe sold by International Medsurg Connection, Reference K022159.

This submission includes piston syringe that will be sold both sterile and non-sterile. Non-sterile syringes are to be sold to OEMs for EtO sterilization according to their validated process per ANSI/AMMI/ISO 11135. Sterile syringes are to be sold directly to users after EO sterilization validation per ANSI/AMMI/ISO 11135

Related items are indicated at the table below.

Category	Device Name	Sterility
Piston syringe	Syringe 1cc Luer Slip	Sterile and Non-sterile
	Syringe 2cc Luer Lock	Sterile and Non-sterile
	Syringe 2cc Luer Slip	Sterile and Non-sterile
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	Syringe 10cc Luer lock	Sterile and Non-sterile
	Syringe 10cc Luer Slip	Sterile and Non-sterile
	Syringe 20cc Luer lock	Sterile and Non-sterile
	Syringe 20cc Luer Slip	Sterile and Non-sterile
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	Syringe 100cc Luer lock	Sterile and Non-sterile
	Syringe 100cc Luer Slip	Sterile and Non-sterile

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) 12/21/10

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

510(k) Number: K102969