AUG 18 2011 K110656

8. 510(K) SUMMARY

Trade Name:	IMC Blood Collection Needle (non-sterile and sterile)
Common Name:	Blood Collection Needle
Classification Name:	21 CFR 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:	December 22, 2010
Predicate Devices:	• VACUETTE VISIO PLUS blood collection needle (K061483)

Device Name(s):

IMC Blood Collection 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 Blood Collection Needle with the currently marketed:

Description	510(k) Number
VACUETTE VISIO PLUS Blood Collection Needle	K061483

Device Description

This device is intended for use in venous blood collection.

IMC blood collection needles are manufactured from stainless steel sharpened at both ends that is attached to the hub. The hub is threaded on one side to connect with the needle holder which is used to guide the needle into an evacuated blood collection tube. This end of the needle is shorter end and is fitted with a protective rubber sleeve. And a needle cap. The opposite end of the needle is 1" or 1 ½" for withdrawing blood. The two needle caps protect the needle and maintain the sterility. The seal between the two needle caps is covered with a perforated paper label that simplifies identification and acts as a seal of integrity.

IMC blood collection needles are a sterile single use disposable product. The needles are non-toxic and non-pyrogenic and are available in a variety of combinations of needle sizes (20 to 22 gauge) and needle lengths (1" and 1 ½').

Statement of Intended Use

Indications For Use: This device is intended for use in venous blood collection

Name/Description

Description	Size	Sterility
20 Gauge Blood collection needle	1"and 1 ½"	Sterile & Non-sterile
21 Gauge Blood collection needle	1"and 1 ½"	Sterile & Non-sterile
22 Gauge Blood collection needle	1"and 1 ½"	Sterile & Non-sterile

New Devices as Compared to Marketed Device(s)

The IMC Blood Collection Needle and the predicate device 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 Blood Collection Needle	VACUETTE VISIO PLUS Blood Collection Needle: K061483 (Predicate)
Intended Use	This device is intended for use in venous blood collection.	This device is intended for use in venous blood collection.
Material		
Needle cap	HDPE	Similar
Resistance cover	Rubber (Synthetic)	Similar
Hub	ABS	Similar
Label	30g/m2 paper	Similar
Needle (Cannula)	SUS 304	Similar
Needle cap	Polypropylene	Similar
colors		
20G	Yellow color	Yellow color
21G	Deep green color	Green color
22G	Black color	Black color
Length	1"and 1 ½"	1"and 1 ½"
Gauge	20G, 21G & 22G	21G & 22G
Cover dimension	1" size: 47mm 1 ½" size: 47mm	1" size: 47mm 1 ½" size: 47mm
Cover color	White (for all gauges)	Clear (for all gauges)

Feature/ Characteristic	IMC Blood Collection Needle	VACUETTE VISIO PLUS Blood Collection Needle: K061483 (Predicate)
Tip configuration	Bevel	Bevel

Performance Data:

Performance Characteristics	Test Method	Acceptance Criteria	IMC Blood Collection Needle	VACUETTE VISION PLUS Blood Collection Needle K061483
Hub/needle bond strength	ISO 7894 :1993	20G : >54N 21G: >44N 22G: >40N	Meets Standard Criteria	Meets Standard Criteria

Conclusions:

The indications for use, technology, specification, safety of the IMC Blood Collection Needle and the predicate devices K061483 are essentially the same. The differences between the Blood Collection Needle are minor and do not raise new issues of safety or effectiveness. Hence, the IMC Blood Collection 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

AUG 18 2011

Re: K110656
Trade/Device Name: IMC Blood Collection Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
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, 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 Blood collection needle

Indications For Use: This device is intended for use in venous blood collection.

Name/Description

Gauge	Size	Sterility
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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)

8/18/4

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

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