NOV 19 2010

K102010

Section 5 – 510(k) Summary	Page 5-1

Date Prepared: July 13, 2009

Submitter / Contact:

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Applicant / 510(k) Owner:

MedPro Safety Products, Inc
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Lexington, KY 40505
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Contact Person – Mrs. Tammy Nichols

Name of Device

Trade Name: VACUETTE® PREMIUM Safety Blood Collection Set
Common Name: Safety device for blood collection
Classification Name: Hypodermic Single Lumen Needle with antistick syringe
Regulations No: 21 CFR 880.5570
Product Code: FMI

Predicate Information

Predicate Device: VACUETTE SAFETY BLOOD COLLECTION SET
510(k) Number: K011786
Date of Concurrence: 07/12/2001

Predicate Device: BD VACUTAINER PUSH BUTTON BLOOD COLLECTION SET
510(k) Number: K011984
Date of Concurrence: 08/29/2001

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR §807, Subpart E, under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

Trade or propriety name or model of this device: VACUETTE® PREMIUM Safety Blood Collection Set;

Gauge	Tubing	Accessory	Accessory	Accessory
21	10	Female Luer	Male Luer	
23	10	Female Luer	Male Luer	
25	10	Female Luer	Male Luer	
21	19	Female Luer	Male Luer	
23	19	Female Luer	Male Luer	
25	19	Female Luer	Male Luer	
21	30	Female Luer	Male Luer	
23	30	Female Luer	Male Luer	
25	30	Female Luer	Male Luer	
21	10	Female Luer	Male Luer	Greiner Bio-One Standard Holder
23	10	Female Luer	Male Luer	Greiner Bio-One Standard Holder

Gauge	Tubing	Accessory	Accessory	Accessory
25	10	Female Luer	Male Luer	Greiner Bio-One Standard Holder
21	19	Female Luer	Male Luer	Greiner Bio-One Standard Holder
23	19	Female Luer	Male Luer	Greiner Bio-One Standard Holder
25	19	Female Luer	Male Luer	Greiner Bio-One Standard Holder
21	30	Female Luer	Male Luer	Greiner Bio-One Standard Holder
23	30	Female Luer	Male Luer	Greiner Bio-One Standard Holder
25	30	Female Luer	Male Luer	Greiner Bio-One Standard Holder
21	10	Female Luer	NA	
23	10	Female Luer	NA	
25	10	Female Luer	NA	
21	19	Female Luer	NA	
23	19	Female Luer	NA	
25	19	Female Luer	NA	
21	30	Female Luer	NA	
23	30	Female Luer	NA	
25	30	Female Luer	NA	

Product Description:

The Vacuette Premium Safety Blood Collection Set is a single use, individually wrapped, sterile winged blood collection needle with an integrated needle and safety shield bonded to a flexible tubing with a female luer adapter allowing the set to be used with a luer system (e.g. Holdex®). It is available with optional Luer Adapter and / or Luer Adapter + Holder. The device is free of PVC, DEHP, Latex.

Indications for Use:

"VACUETTE® PREMIUM Safety Blood Collection Set is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated automatically to cover the needle immediately following blood collection thus preventing accidental needlestick injury."

~~Intended Use:~~
~~The Vacuette Premium Safety Blood Collection Set is used in routine venipuncture procedures. It is used for blood collection. The winged needle is designed with a safety shield, which is activated automatically to cover the needle immediately following blood collection to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.~~

Substantial Equivalence:
The VACUETTE® PREMIUM Safety Blood Collection Set is substantially equivalent to the Vacuette Safety Blood Collection Set (K011786) and the BD Pushbutton Butterfly (K011984).

Simulated Use Testing:
Simulated use testing was performed by a panel of health care professionals to evaluate function and performance, ease of use and other functions of the safety feature.

Material Testing:
The VACUETTE® PREMIUM Safety Blood Collection Set will meet ISO 10993-1 requirements for material safety and biocompatibility, per product category:

- External Communicating
- Blood Path Indirect
- Contact Duration "A" (Limited)

Conclusions:
Summary of Safety and Effectiveness –
The device has a release mechanism molded into the needle shield. During the blood collection process, as the user performs the initial puncture, release of the wings causes them to fall open and brings the needle shield into a staged position. When the user is ready to remove the device, they grasp the wings as they would during routine use, and upon closing the wings, the needle shield is deployed and covers the needle upon exit.

The device is substantially equivalent to the predicate devices (VACUETTE® Safety Blood Collection Set and BD Vacutainer Push Button Set) because it has a plastic safety shield that covers the needle

after it has been contaminated, protecting the healthcare worker from a potential needlestick. The predicate VACUETTE® Safety Blood Collection Set's safety shield is activated when the user manually slides the shield over the needle after use. The predicate BD Vacutainer Push Button Blood Collection Set's safety shield is activated when the user manually presses the button located on the top of the device, activating the spring mechanism to deploy the safety shield. The VACUETTE® PREMIUM Safety Blood Collection Set's safety shield is automatically activated when the user closes the wings to withdraw the device from the patient. The spring loaded safety shield covers the needle after it has been contaminated, protecting the healthcare worker from a potential needlestick.

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

MedPro Safety Products, Incorporated
C/O Mr. H. Carl Jenkins
Wood Burditt Group
10 E. Scranton Avenue, Suite 201
Lake Bluff, Illinois 60044

NOV 19 2010

Re: K102010
Trade/Device Name: VACUETTE® PREMIUM Safety Blood Collection Set
Regulation Number: 21 CFR 880.5570
Regulation Name:
Regulatory Class: II
Product Code: JKA, FMI
Dated: November 5, 2010
Received: November 8, 2010

Dear Mr. Jenkins:

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.

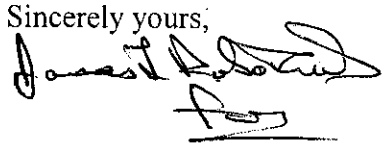
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Section 4 - Indications for Use Statement	Page 4-1

Indications for Use

510(k) number (if Known): K102010

NOV 19 2010

Device Name: VACUETTE® PREMIUM Safety Blood Collection Set

Indications for Use:

"VACUETTE® PREMIUM Safety Blood Collection Set is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated automatically to cover the needle immediately following blood collection thus preventing accidental needlestick injury."

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC

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

510(k) Number: K102010