K072602

JUN 18 2008

SECTION V

510(k) SUMMARY

Contact:
510(k) Owner's Name – MedPro Safety Products, Inc.
Address – 817 Winchester Road, Suite 200, Lexington, KY 40505
Phone – (859) 225-5375
Facsimile – (859) 225-5347
Contact Person – Mr. Walter Weller
Date of Summary – September 12, 2007

Name of Device:
Trade or Proprietary Name - VACUETTE® PREMIUM Safety Needle System
Common Name – Safety device for blood collection
Classification Name – Hypodermic single lumen needle with antistick syringe
(21 CFR 880.5570, Product Code FMI and 21 CFR 880.5860, Product Code MEG)

Predicate Device: The Guarded Needle 2000
510(k) Number: K003406
Date of Concurrence: January 21, 2001

Predicate Device: BD Vacutainer Passive Shielding Blood Collection Needle
510(k) Number: K003461
Date of Concurrence: February 1, 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:

Product Description
The VACUETTE® PREMIUM Safety Needle System is a single use, sterile holder designed with an integrated, multiple sample needle and safety shield to provide protection against needlestick injury during venipuncture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2008

Medpro Safety Products, Incorporated
C/O Mr. Greg E. Mitchell
Frost Brown Todd, LLC
250 West Main Street, Suite 2700
Lexington, Kentucky 40507-1749

Re: K072602
Trade/Device Name: VACUETTE® PREMIUM Safety Needle System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI, MEG
Dated: June 11, 2008
Received: June 12, 2008

Dear Mr. Mitchell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012602

INDICATIONS FOR USE

510(k) Number (if known): New submission

Device Name: VACUETTE® PREMIUM Safety Needle System

Indications for Use:
The VACUETTE® Premium Safety Needle System is used in routine venipuncture procedures. The holder is designed with an integrated, multiple sample needle and safety shield. Upon insertion of the first blood collection tube, the safety shield is automatically released. The safety shield covers the needle immediately following blood collection from the patient. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Anthony D. Watson

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

510(k) Number: K012602