K043328

APR 15 2005

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): DKS Loversan Industria Biomedica SPA
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Contact Person: Alessandro Corradi

Date of Summary: November 1, 2004

Trade/Proprietary Name: MICROFLO-SAFE Scalp Vein Set

Classification Name: Set, Administration, Intravascular

Product Code: FPA

Predicate Device:

Surshield Safety Winged Blood Collection Set – Terumo Medical Products K031279
Unlok Plus Infusion Set - Myco Medical Supplies, Inc. K000592
VacuFlow + Safe Collection Set – MED-PRO Technologies K000714

Intended Use:

The MICROFLO-SAFE Scalp Vein Set is a winged blood collection needle intended for veinpuncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adaptor from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

DKS Loversan Industria Biomedica SPA
C/O Mr. Arthur Ward
Consultant
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K043328
Trade/Device Name: MICROFLO-SAFE Scalp Vein Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 10, 2005
Received: March 14, 2005

Dear Mr. Ward:

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

Indications for Use

510(k) Number (if known): K043328

Device Name: MICROFLO-SAFE Scalp Vein Set

Indications for Use:

The MICROFLO-SAFE Scalp Vein Set is a winged blood collection needle intended for veinpuncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adaptor from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(510(k) Number: K043328