K021102

MAY 0 8 2002

510(k) SUMMARY

Dr. Emily Iker's DM Sleeve™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Jonathan S. Kahan

Date Prepared: April 4, 2002

Name of Device and Name/Address of Sponsor

Emily Iker, M.D., A.P.C.
2021 Santa Monica Boulevard
Suite 620E
Santa Monica, CA 90404
Phone: (310) 829-7472
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Common or Usual Name

Compression Sleeve

Classification Name

Medical Support Stocking

Predicate Devices

D.R. Medical Controlled Pressure Garments (K001300), Jobst Elvarex Compression Garments (K963573), and Jobst Ready-To-Wear Arm Sleeves (K991570).

Intended Use

The DM Sleeve™ is intended to be used to apply pressure to the extremities and is indicated for use in the management of:

Lymphedema and other edematous conditions, phlebitis, and vascular malformations.

Technological Characteristics and Substantial Equivalence

The DM Sleeve™ is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics. Both the DM Sleeve™ and its predicates are intended to apply pressure to the extremities to manage lymphedema and other edematous conditions, phlebitis, and vascular malformations.

The DM Sleeve™ has very similar components as its predicate devices and very similar technological characteristics. Like the Jobst Elvarex Compression Garments (K963573), the DM Sleeve™ consists of a cotton and nylon fabric, which is fitted to the extremity. The DM Sleeve™ and the D.R. Medical Controlled Pressure Garments (K001300) apply non-gradient pressure to move interstitial fluid into venous and lymphatic channels. The DM Sleeve™ applies pressure by means of foam protrusions, while the Jobst Ready-To-Wear Arm Sleeves (K991570) use spandex and nylon. However, both devices raise the same issues of safety and effectiveness, and are therefore substantially equivalent.

Performance Data

The DM Sleeve™ underwent safety testing to assure that the product retained its size and shape after washing. In all instances, the DM Sleeve™ functioned as intended and the results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Emily Iker , M. D., A.P.C
C/O Mr. Jonathan S. Kahan
Hogan & Hartson, LLP
555 Thirteenth Street
Washington, DC 20004

MAY 0 8 2002

Re: K021102
Trade/Device Name: DM Sleeve™
Regulation Number: 880.5780
Regulation Name:
Regulatory Class: II
Product Code: DWL
Dated: April 4, 2002
Received: April 4, 2002

Dear Mr. Kahan:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021102

INDICATIONS FOR USE FORM

510(k) Number (if known): K

Device Name: DM Sleeve™

Indications for Use: The DM Sleeve™ is intended to be used to apply pressure to the extremities and is indicated for use in the management of:

Lymphedema and other edematous conditions, phlebitis, and vascular malformations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021102