SEP 1 9 2002

K022786

Huntleigh
HEALTHCARE

510(k) SUMMARY
DVT60 Limb Compression Sleeves

Company	Huntleigh Healthcare Inc 40 Christopher Way Eatontown New Jersey
Contact	Audrey Witko Phone 732 578 9898 Fax 732 460 5809
Summary Preparation Date	1ST August 2002
Trade Name	DVT60
Common Name	Limb Compression Sleeves
Classification Name	Sleeve, Limb, Compression (JOW)
Predicate Device	Huntleigh Healthcare DVT10(s) K925717/A
Device Description	The DVT60 Compression Sleeves are single chamber inflatable cuffs, designed to fit around a patient's calf. They are used with the Huntleigh Flowtron Excel and Universal Pumps. When inflated, they compress the veins in the calf and expel blood out of the leg, promoting circulation and overcoming stasis.
Intended Use	DVT60 sleeves are designed to help prevent Deep Vein Thrombosis (DVT), by increasing venous blood flow.

Summary of Technological Characteristics

The DVT60 compression sleeves have the same technological characteristics as the DVT10 predicate device.
The design characteristics, materials, and method of manufacture are the same,
When compared to the predicate device, the DVT60 sleeves are extended in width, so that are suitable to fit a patient's calf of up to 28 inches circumference.

Determination of Substantial Equivalence

The determination of Substantial Equivalence is based on non-clinical outcome, inflation performance testing. The sleeves are tested by fitting to a subject's calf and observing the increase in velocity of the blood flow in the veins during compression.

Equivalence Testing Results

The sleeves are made from similar materials and compress a similar area of the patient's limb. The inflation sequence and pressures are the same.

The venous blood velocity increase and duration are similar to the predicate device. This increase in blood velocity overcomes venous stasis and so helps to prevent deep vein thrombosis, in the same manner as the predicate device.

Therefore, we propose that the clinical treatment that the patient receives will be equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

Huntleigh Healthcare, Inc.
c/o Ms. Audrey Witko
Vice President, Corporate & Clinical Affairs
40 Christopher Way
Eatontown, NJ 07724

Re: K022786
Trade Name: DVT60
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compression
Regulatory Class: Class II (two)
Product Code: JOW
Dated: May 23, 2002
Received: August 22, 2002

Dear Ms. Witko:

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) 594-4646. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
DVT60 Limb Compression Sleeves

Ver/3 – 4/24/96

Applicant: Huntleigh Healthcare Inc.

510(k) Number (if known): Not known at present

Device Name: DVT60

Indications For Use:

The DVT60 Compression Sleeve is designed to help prevent Deep Vein Thrombosis (DVT), by increasing venous blood flow.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022786

Prescription Use X (Per 21 CFR 801.109)
(Per 21 CFR 801.109)

(Optional Format 1-2-96)