K022233

AUG 1 2 2002

510(k) Summary

HydroBoot

Common/Classification Name: Medical Support Stocking
To Prevent the Pooling of Blood in the Legs, 21 CFR 880.5780(a)

Incappe, Inc.
1529 Walnut Street
Vicksburg, MS 39180

Contact: Dr. Henk Kuiper, Prepared: July 5, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The Hydroboot is substantially equivalent to: the Geen Medisox, cleared by FDA as K981296 on May 29, 1998; to the Jobst Elvarex Compression Garment, cleared by FDA as K963573 on October 16, 1996; and, to the Pneumatic Ambulatory Compression System, cleared by FDA as K020538 on May 15, 2002.

B. DEVICE DESCRIPTION

The HydroBoot device is intended to provide compressive therapy on the lower legs and feet to help manage chronic swelling and ulceration due to venous insufficiency and lymphedema. The HydroBoot achieves its pressure against the foot and leg from the hydrostatic pressure of water that fills the walls of the boot. The pressure depends only on the depth of the water, so a pressure gradient from the foot to the knee is obtained.

C. INTENDED USE

The HydroBoot device is indicated to provide compressive therapy on the lower legs and feet to help manage chronic swelling and ulceration due to venous insufficiency and lymphedema.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Incappe Hydroboot is within a type of device called Medical Support Stocking to Prevent the Pooling of Blood in the Legs. The HydroBoot indications for use is slightly different from those of the legally marketed predicate devices, but the differences do not affect the intended therapeutic use. The HydroBoot has somewhat different technological characteristics from those of the predicate devices. However, the differences do not raise new types of questions of safety and effectiveness. Accepted scientific methods exist to determine the pressure levels produced in the HydroBoot and these methods have demonstrated that the HydroBoot is equivalent to the predicate devices in producing a therapeutic level

of pressure on the foot and lower leg. This leads to a decision of substantial equivalence.[1]

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the HydroBoot are somewhat different from the predicate devices. The predicate devices depend on mechanical forces from an elastic fabric to produce the pressure on the foot and leg. The pressure in the HydroBoot results from the hydrostatic pressure of water that fills the walls of the HydroBoot.

F. TESTING

Testing using pressure sensors was carried out on volunteers as they walked and performed other maneuvers while wearing the HydroBoot or elastic wrap. The pressure measurements confirm the values predicted from the height of the water column and show the effect of walking on the pressure levels.

G. CONCLUSIONS

This pre-market notification demonstrates Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Incappe, Incorporated
C/O Robert Sheridan
R. Sheridan Associates
632 Dundee Drive
Wilmington, North Carolina 28405

Re: K022233
Trade/Device Name: HydroBoot
Regulation Number: 880.5780 (a)
Regulation Name: Medical Support Stocking
Regulatory Class: I I
Product Code: DWL
Dated: July 5, 2002
Received: July 11, 2002

Dear Mr. Sheridan:

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.

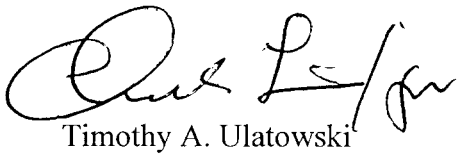
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K022233

Device Name: HydroBoot

Indications For Use:

The HydroBoot provides comprehensive therapy on the lower legs and feet to help manage chronic swelling and ulceration due to venous insufficiency and lymphedema.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K022233