K971026

510 (K) Summary

This summary was submitted by:

AUG 14 1997

Richard S. Dillon M.D.
Circulator Boot corp.
150 Mill Creek road
Ardmore PA, 19003

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The contact person is:

Deborah Welker
Administrator

This Summary was prepared on 3/11/97

The device name is:

The Circulator Boot

The Circulator Boot description:

The Circulator Boot is an end diastolic pneumatic compression device made up of several components. A double walled plastic bag is placed over the leg of the patient and then placed inside a rigid plastic "boot". The boot is then attached to a valve system which is connected to an air supply. The valve is also connected to an EKG QRS monitor that times the compression cycle to occur after a variable (operator selectable) delay following the QRS signal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Richard S. Dillion, M.D.
Circulator Boot Corporation
150 Mill Creek Road
Ardmore, Pennsylvania 19003

AUG 14 1997

Re: K971026
The Circulator Boot
Regulatory Class: III (Three)
Product Code: 74 (DRN)
Dated: April 10, 1997
Received: April 29, 1997

Dear Dr. Dillion:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use:

The Circulator Boot System - alone or in combination with other drug or device therapies - may be used to treat:

- peripheral arterial disease
- ischemic lesions
- claudication pain
- necrotizing cellulitis
- venous stasis ulcers
- stasis dermatitis
- chronic lymphedema
- thrombophlebitis

Division Sign-Off
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K971026

It is classified as:

A class III device

The Circulator Boot is equivalent to:

1. The Circulator Boot (original model) 510(k) # K792354
2. The Jobst Extremity Pump 510(K) # K882683
3. Cardiassist 510(K) # K792430

Product	Device description	Difference from Circulator Boot
Cardiassist	Water pressure applied from groin to midcalf timed with heartbeat to maximize coronary blood flow.	Blocks blood flow into the legs and blocks venous and lymphatic flow out of the lower leg.
Jobst Extremity pump	Treatment of lymhpedematous states associated with venous insufficiency or blockage of the lymphatic system.Cloth boots of various lengths are inflated for various periods of time to intermittently pump fluid from the legs.	soft cloth boots are used. Inflation is only in late diastole so that arterial blood flow into the leg is not blocked.
Circulator Boot (original model)	Essentially the same use as the new model without the increased accuracy of timing and easier user interface.	Old model monitor without the more accurate timing. Old model could vary timing by as much as +/- 0.05 seconds, new model is accurate to within +/- 0.002 seconds.