K082134

Premarket Notification 510(k) Summary
As required by section 807.92

This summary was submitted by:

Richard S. Dillon, M.D.
Circulator Boot Corporation
72 Pennsylvania Avenue
Malvern, PA 19355
FDA Registration number: 2518635
Telephone number: 610-240-9980 (Circulator Boot Corp Office)
Fax: 610-240-9982
Dr. Dillon @ home office: 610-527-0874

MAY - 7 2009

Contact person: Richard S. Dillon, M.D.
1260 Round Hill Rd.
Bryn Mawr PA 19010
Telephone: 610-527-0874

Date this summary prepared: 11/30/2008

Device name:

Proprietary name: Multicrus Circulator Boot Systems
Common name: End-diastolic boot
Current Classification:

Listing Number	Listing Status	Product Code	Device Name
D033631	Active	DRN	Enhanced External Counter Pulsation
Q012536	Active	IPM	Cover. Limb
Q013236	Actice	HWN	Instrument, Compression

Name of device component originating this submission: Multicrus Boot.

NAMES OF LEGALLY MARKETED DEVICES FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3):

Circulator Boot - K792354 (1980) - End-diastolic therapy using Long rigid boots for treatment of leg vascular diseases and congestive heart failure

Circulator Boot - K833627/A (1984) – Modification of end-diastolic therapy to limit area of treatment to specific area needing the therapy: the lower leg. The Miniboot.

Circulator Boot - K971026 (1997) – Addition of computer in heart monitor to automate the function of the attending boot technician in continually adjusting the delay time after the detected

QRS complex to allow the preset compression time to occur in end-diastole and to end 0.04 seconds before the next QRS complex. Thus, maximal inflow of blood into the leg is allowed before boot compressions and a maximum reduction in afterload is produced to assist the heart. A nomogram allows therapy in cases of atrial fibrillation.

Vasomedical and CardioMedics: K020857and K22107. Indications approved for the latter include ischemic heart disease, congestive heart failure, angina pectoris, myocardial infarction and cardiogenic shock.

DEVICE DESCRIPTION as required by 807.92(a)(4):
The Circulator Boot Systems are designed to allow pneumatic compression therapy to any extremity (its whole or a part) as prescribed by a physician. A computer within a heart monitor delays compressions after the detection of the QRS complex to allow maximum inflow of blood into the extremities and signals release of the extremity 0.04 seconds before the time of the next QRS complex to maximally reduce afterload and heart work. The part to be treated is first placed into a double-walled plastic disposable bag (legs or arms) or enclosed by a small cuff (such as an elbow). The bagged extremity is then placed within a rigid plastic boot which is adjusted to limit the dead space around the leg. In the case of K792354, adjustment for differences in the length of the extremity is made by applying one of three different length Long Boots ("A". "B" or "C") while adjustments in the width of the extremity is made by moving inner walls snuggly against the part; adjustments for the A-P (anterior-posterior) dimension are accomplished by arcing the thick plastic aprons attached to the inner side of the lateral movable walls tightly down over the extremity.

The new "Multicrus" boot **K082134** is likewise a rigid plastic boot but telescoping and adjustable in all three dimensions: length, height and width to minimize the space around the bagged leg. It is composed of eight overlapping right-angled plastic pieces which are applied firmly against the extremity. Thus, a piece might be placed under the thigh and knee and against the inner part of the leg (as high up the leg as desired). A second piece may be placed against the lateral aspect of the thigh and knee with its bottom section under the first part. These two parts are pushed together to snuggly hug the inner and lateral parts of the extremity. A third part may then be placed against the inner calf and under the heel and distal part of the first part. A fourth part is placed against the lateral calf and foot and under the heel and the third part and under the second part. The third and fourth parts are again pushed together to snuggly hug the calf and foot. The vertical wall of the fifth part is placed between the vertical walls of the first and third parts while its horizontal wall is placed over the upper leg, again as far up the leg as desired. The vertical wall of the sixth part is placed between the vertical walls of the second and fourth parts and its horizontal part is placed to overlap the thigh and the fifth part. Finally, a seventh and eighth part are placed over the top of the lower leg and foot and over the distal horizontal aspects of the fifth and sixth parts and again are pushed together to minimize the dead space around the

lower leg. All are held in place by Velcro patches between the overlapping parts and by straps surrounding the assembled boot.

The valve assembly is attached to a plate included on the top of the eighth part and connected then to the compressed air line and the heart monitor. The technician adjusts the pressure knob of the valve assembly as needed to achieve the desired pressure in all of the boot systems. Desired pressures were gained in every patient treated with the Multicrus boot during its five weeks of clinical usage. With all of our boot systems, the physician is encouraged to improvise as necessary to treat patients with special needs (e.g. deformed legs that cannot be straightened out sufficiently to enter our rigid boots). A small cuff is one such improvisation that has allowed treatment of portions of any extremity in concert with treatment of the legs in the Long Boots. This small "Cuff Boot"consists of a juvenile blood pressure cuff to surround the extremity (perhaps a tennis elbow) with a bladder from an adult blood pressure cuff connected to both it and a air-bulb. The bladder is placed over the thigh and beneath the plastic airbag of the Long Boot and, hence, is compressed simultaneously with the leg. The small cuff applies pressure in end-diastole with the same pressure introduced into the Long Boot.

INTENDED USE as required by 807.92(a)5)
Indications for Use:

2008 Indications and Contraindications for the Circulator Boot Systems

"Indications: The Circulator Boot System alone – or in combination with other drug or device therapies – may be prescribed by the physician to treat:

Poor arterial flow in extremities associated with:

- Ischemic ulcers
- Rest pain or claudication (pain with walking)
- Threatened gangrene
- Insufficient blood supply at an amputation site
- Persisting ischemia after embolectomy or bypass surgery
- Pre- and post-arterial reconstruction to improve runoff

Diabetes complicated by the above or other conditions possibly related to arterial insufficiency including:

- Nocturnal leg cramps
- Necrobiosis diabeticorum

Venous diseases (once risk of emboli minimized):

- Prophylaxis of deep vein thrombophlebitis
- Edema and induration associated with chronic venous stasis
- Venous stasis ulcers

Athletic injuries: "Charlie horses", pulled muscles, and edematous muscles

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF MULTICRUS BOOT DEVICE COMPARED TO THE PREDICATE LONG BOOT DEVICES K792354 (as required by 807.92(a)(6)

The Multicrus Boot is substantially equivalent in safety and effectiveness to the legally marketed (predicate) "A", "B" and "C" adjustable boots (K792354). They function similarly, share the same scientific principles, may be used for the same indications, share the same construction materials. They differ in that the predicate boots have adjustable interiors in two dimensions: the width and anterior-posterior height of the leg; the Multicrus boot in addition has an adjustable length. Improvisations like the small Cuff Boot are in keeping with the overall medical goals of the Circulator Boot Systems. In the case of the Cuff Boot, a rigid boot is not necessary because of the small volume of the compressed air required to produce adequate pressures. Past and new labels were included in the notebook submitted October, 2008.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807 .92(b)(1Y)3)
The Circulator Boot Systems are normally applied and operated by a trained nurse, physical therapist, technician or doctor. Lay personnel have been successfully trained in its usage to treat patients under the supervision of a physician. Again, trained lay personnel under the supervision of their doctor have successfully treated family members in the home. Necessary precautions and warnings are stated in the Manual. The Verification and Validation data was accumulated in the clinic.

CONCLUSION: The summary above shows that there are no new questions of safety and effectiveness for the Multicrus Boot as compared to the predicate device.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Circulator Boot Corporation
c/o Richard S. Dillon, M.D.
72 Pennsylvania Avenue
Malvern, PA 19355

Re: K082134
Circulator Multicrus Boot System
Regulation Number: 21 CFR 870.5225
Regulation Name: Counter-Pulsating, External Device
Regulatory Class: Class III
Product Code: DRN
Dated: March 7, 2009
Received: March 13, 2009

Dear Dr. Dillon:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

STATEMENT: INDICATION FOR USE

510 (k) Number K082134 _____

Device Name: Circulator Multicrus Boot

Indications for Use:

2008 Indications and Contraindications for the Circulator Boot Systems

"**Indications**: The Circulator Boot System alone – or in combination with other drug or device therapies – may be prescribed by the physician to treat:

Poor arterial flow in extremities associated with:

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Prescription Use ___X__ Over the Counter Use _____

(Part 21 CFR 801 Subpart D) and/or (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082134