

DEC 14 1998

K981643



P.O. BOX 1179 • CUYAHOGA FALLS, OH 44223-0179 • 1 (800) 837-0529 • FAX (216) 686-0597

November 4, 1998

Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: **510(k) Summary, K981643**

Contact Person: Karen L. Diehl, RN
P.O. Box 1179
Cuyahoga Falls, OH 44223
1-800-837-0529

Device Name: RTM DVT PS100 ProSoft Cuff

Common Name: Compression Cuff

Classification Name: Powered, inflatable tube massager, calf cuff
CFR Section: 890.5650

* Claiming Substantial Equivalence to Huntleigh Flowtron DVT System L501 Garment (K881632).

Description: The RTM DVT PS100 ProSoft Cuff is a cotton garment designed to be wrapped around the lower extremity (calf), secured with looped tape and connected to Huntleigh DVT Flowtron pump. The outer shell of the garment is a blend of cotton and linen and encases a plastic inflatable bladder that is connected to the pump via poly vinyl tubing.

Intended Use: This product is intended for use with the Huntleigh DVT Flowtron pump to aid in the prevention of deep vein thrombosis in surgical, trauma and certain medical patients at risk for DVT formation. It is not intended for use on patients with known DVT or with any other intermittent compression device. This device is restricted to sale by or on the order of a physician.

Technological Characteristics:

The RTM DVT PS100 ProSoft Cuff and the Huntleigh L501 garment operate essentially the same technologically with virtually no differences detected during testing. They are both plastic bladders connected to the Huntleigh DVT Flowtron pump, inflated intermittently and applied to the lower extremities for DVT prevention.

To determine that the two devices are technologically equivalent RT Medical conducted an "Air Flow/Volume Test" and a "Cycle Test." The Air Flow/Volume Test consisted of inflating the RTM bladder and the Huntleigh L501 bladder and timing the inflation and deflation times. They were found to be almost identical with less than one second differences detected in the inflation/deflation times. The Cycle Test was accomplished in the same manner, however, the garment was attached to a person's calf to provide counter pressure and mimic a clinical environment. Inflation/deflation times for both cuffs were obtained and recorded with, again, virtually no difference in the times detected. The conclusion was drawn that the two devices are technologically and substantially equivalent.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen L. Diehl
Director, Clinical Support Services
R.T. Medical Services, Inc.
730 W. Portage Trail Extension
Akron, OH 44313

Re: K981643
RTM DVT ProSoft Cuff Model Number PS100
Regulatory Class: II (Two)
Product Code: JOW
Dated: November 5, 1998
Received: November 12, 1998

Dear Ms. Diehl:

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 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). 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.

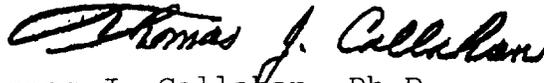
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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.

Page 2 - Ms. Karen L. Diehl

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/dsma/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): K981643

Device Name: RTM DVT ProSoft Cuff

Indications For Use:

This product is intended for use with the Huntleigh DVT Flowtron pump to aid in the prevention of deep vein thrombosis in surgical, trauma and certain medical patients at risk for the formation of DVT. It is not intended for use on patients with known DVT or with any other intermittent compression device. Federal law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean R. Sampson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 98 1643

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)