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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

January 7, 1999

**WARNING LETTER
CIN-WL-99-082
REQUESTED**

**CERTIFIED MAIL
RETURN RECEIPT**

Mr. Thomas S. Shaw, Vice President
RT Medical Services, Inc.
P.O. Box 1179
Cuyahoga Falls, Ohio 44223

Dear Mr. Shaw:

On December 3,4,7,8&9, 1998, the Food and Drug Administration (FDA) conducted an inspection of your firm which manufactures the RTM DVT Pro Soft Cuff. The reusable compressible limb is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The investigator found deviations from the Quality System Regulation, Good Manufacturing Practice (GMP) for Medical Devices as listed in Part 820 of Title 21, Code of Federal Regulations (CFR). This causes the RTM DVT Pro Soft Cuff to be adulterated with the meaning of Section 501(h) of the Act, in that the methods used in or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Quality System Regulation, Part 820.

The following deviations from the Device Quality Regulations were documented:

1. Failure to establish and maintain a quality assurance program that is specific for the RTM DVT Pro Soft Cuff.
2. Failure to establish and maintain a Device Master Record for the RTM DVT Pro Soft Cuff.
3. Failure to establish and maintain a Device History Record to ensure that each lot is manufactured in accordance with the Device Master Record.
4. Failure to establish a procedure for implementing corrective and preventive actions.
5. Failure to establish a procedure for a quality audit. A quality audit has not been conducted.
6. Failure to establish a Medical Device Reporting (MDR) Procedure.
7. Failure to establish a procedure for controlling design changes.
8. Failure to establish and maintain a complaint and/or recall procedure.
9. There are no records indicating production equipment such as the pressure gauge used to measure the pressure of each bladder before release is calibrated.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be

symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

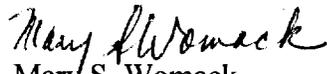
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within fifteen (15) days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,


Mary S. Womack
Acting District Director
Cincinnati District

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