K123398

DEC 1 8 2012

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Renfro Corporation
DATE PREPARED:	October 31, 2012
CONTACT PERSON:	Rebecca K Pine Renfro Corporation PO Box 908 611 Linville Road Mount Airy, NC 27030 Phone: (760) 809.5178
TRADE NAME:	Dr. Scholl's Compression Socks
COMMON NAME:	Compression Socks
CLASSIFICATION NAME:	Medical Support Stockings
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 880.5780
PRODUCT CODE	DWL
PREDICATE DEVICES:	Elastic Therapy, Inc. Rx Fit Medical Socks (K925643)

Substantially Equivalent To:
The Renfro Compression Socks are substantially equivalent in intended use, principal of operation and technological characteristics to the Elastic Therapy, Inc. Rx Fit Medical Socks (K925643).

Description of the Device Subject to Premarket Notification:
The Renfro Compression Socks are devices intended to help prevent pooling of blood and fluid to the extremities by applying controlled pressure. The Renfro compression socks are knitted using yarns made of nylon, polyester, cotton and spandex.

Indication for Use:
The Renfro Compression Socks are intended to help prevent pooling of blood in the legs by controlled pressure in the legs and help prevent deep vein thrombosis (DVT), edema and leg discomfort in individuals subjected to immobility.

Technical Characteristics:
The Renfro Compression Socks have similar physical and technical characteristics to the predicate devices. These characteristics are tabulated below:

Characteristics	Renfro Compression Socks	Elastic Therapy, Inc, Rx Fit Medical Socks
Function	Prevent pooling of blood in legs	Prevent pooling of blood in legs
Principle of Operation	Application of controlled pressure	Application of controlled pressure
Anatomical Site	Foot/leg	Foot/leg
Prescription/ over-the-counter use	Over-the-counter	Over-the-counter

Performance Data:
All necessary performance testing has been conducted for the Renfro Compression Socks to assure substantial equivalence to the predicate devices and demonstrate the devices perform as intended. All testing was performed on test units representative of finished devices. Testing included:

- Comparative compression strength

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Renfro Compression Socks are determined by Renfro Corporation, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2012

Ms. Rebecca K. Pine
Renfro Corporation
PO Box 908
661 Linville Road
MOUNT AIRY NC 27030

Re: K123398
Trade/Device Name: Renfro Compression Socks
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: October 31, 2012
Received: November 5, 2012

Dear Ms. Pine:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123398

Device Name: **Renfro Compression Socks**

Indications for Use:

The Renfro Compression Socks are intended to help prevent pooling of blood in the legs by controlled pressure in the legs and help prevent deep vein thrombosis (DVT), edema and leg discomfort in individuals subjected to immobility

AND/OR

Prescription Use _____ (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_X____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.12.18 13:15:58 -05'00'

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

510(k) Number: K123398