K073013

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Contact Person

Doug Hale
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Order Line: 517-420-8204 Fax: 517-622-3265

NOV 2 1 2007

2. General Information

Name:	Compression Technologies Unlimited Inc.
Trade Name:	CTU676 Devices
Classification Name:	Compressible Limb Sleeve
Classification:	This device is classified by the Division of Cardiovascular Devices into Class II, (21 CFR 870.5800)

3. Device Description and Predicate Device Information

The CTU676 devices are used for different forms of compression therapy. The system is an air inflatable garment that is controlled by an electrical air pump. The air pump controls the garment so chambers inflate and deflate sequentially over a period of ~ 85 seconds. Patient or staff operated controls with visual and / or audible alarms for low pressure, high pressure, low battery, and system failures.

The controls use a power on/off switch on the side of the unit. On the front of the unit are fault indicators. The pressure is preset to 52 mmHg. The power on light will flash and stay illuminated when the unit is operating. The charging light will illuminate when batteries are charging.

Principle of Operation

The CTU676 is designed to provide airflow to the garment for the purpose of controlling garment patient interface pressure. The CTU676 is provided with circuitry to sense the pressure in the garment and maintain the selected level of CTU676 output, by increasing or decreasing the effective voltage applied to the air pump.

The CTU676 main components are an air pump, cycle control valve assembly and the pump controller circuit board, which also controls the alarm system.

The output of the pump is sent through 1 or 2 PVC clear tubes that are connected to either 1209 calf garment or the 1205 full leg garment. The cycle control valve controls the airflow to both of the garments simultaneously until preset pressure is reached then holds for 3 seconds and releases for 1 minute.

Component Description

Garment

The garment is composed of a single air cell. It is connected to the pump by a single tube that is integral to the garment. This terminates in a female connector, which attaches to a male connector on the right hand side of the pump, which allows air to flow to each of the garments. The garment sleeve is disposable and intended for use with one patient only. The garments are disposable and for single use only.

CTU676 outer casing

The CTU676 outer case is made out of a high impact ABS plastic housing that contains a pump unit, microprocessor pressure control circuit board, an air control valve, and rechargeable NiMH batteries. Controls are kept to a minimum, comprising of an ON/OFF switch located on the right side of the unit. The output of the CTU676 is sent along a 6ft long tube to the garments. The heart of the system is the microprocessor controller circuit board. This automatically controls the voltage to the air pump thus allowing sufficient airflow to maintain the preset pressure using a pressure sensor feedback circuit. This circuit also contains Audible & Visual alarms.

4. Intended Use

The ***CTU676*** is a prescriptive device that includes continuous enhanced circulation therapy of the lower limbs. The CTU676 is intended for use in the following:

- Enhancing blood circulation
- Reducing wound-healing time.
- Preventing Deep Vein Thrombosis (DVT).
- Diminishing post-operative pain and swelling
- Treatment and assistance in healing: stasis dermatitis
- Venous stasis ulcers; arterial and diabetic ulcers
- Treatment of Chronic venous insufficiency

- Reducing edema

5. Substantial Equivalence Comparison

The CTU Inc. devices are substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- TravelAir™
- DVTcare™ CA5
- WizAir™

The CTU676 System is substantially equivalent in all aspects, e.g., technical characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available predicate devices. The CTU676 System includes an additional cuff for the Foot and Booster cuff for faster inflation of the cell. The pressure profile of the new cuff is similar to Wiz Air System; however, the additional cuff and software modification were verified through bench testing and validation that was performed on healthy volunteers. Testing results showed that the CTU676 performed according to its specifications in operated in a safe and effective manner.

6. Summary of Studies

The function and performance of the CTU676 Systems have been evaluated through non-clinical design verification and validation tests. Testing included mechanical performance evaluations and simulated use tests. The results of the CTU676 System performance evaluations demonstrate that the CTU676 System device design is well suited for its intended use.

CTU Inc. completed mechanical performance evaluations to verify that the CTU676 systems meet the defined design specifications and conform to the safety and performance of the product and to support the compatibility of the internal components. Test results support the electrical and ultrasonic safety, electromagnetic compatibility, and performance of the CTU676 for its intended use.

7. Conclusion (statement of equivalence)

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the CTU676 Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Compression Technologies Unlimited, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K073013
CTU676 Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: October 24, 2007
Received: October 25, 2007

Dear Mr. Job:

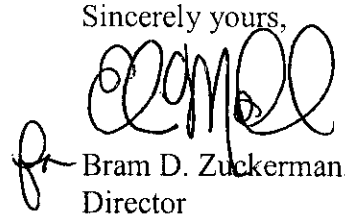
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Compression Technologies Unlimited, Inc.
The Leader in Compression Therapy Products
CTU676

Indications for Use Statement

510(k) Number: Pending

Device Name: CTU676 devices

Indications for use:

The ***CTU676*** is a prescriptive device that includes continuous enhanced circulation therapy of the lower limbs. The CTU676 is intended for use in the following:

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- Treatment of Chronic venous insufficiency
- Reducing edema

Prescription Use ____X_____ (per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 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)

(Division Sign-Off)
Division of Cardiovascular Devices

May 8, 2007

510(k) Number K073013