JUN 2 8 2004

510(k) Summary

SCD Express™ Portable Compression System (PCS)

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: February 26, 2004

1. Contact Person

Bridget Gardner
Manager, Regulatory Affairs
(508)-261-6384

2. Name of Medical Device

Classification Name: Sleeve, Limb, Compressible

Common or Usual Name: Compressible Limb Sleeve Device

Trade Name: SCD Express™ Portable Compression System (PCS)

3. Identification of Legally Marketed Device

The proposed SCD Express™ Controller and Foot Cuff are substantially equivalent in intended use, function and mode of operation to the currently marketed SCD Response™ Compression System (K992079) and Novamedix AVImpad (K953648).

4. Device Description

The SCD Express™ Controller is an intermittent pneumatic compression device for applying sequential, gradient pressure to a patient's legs for the prevention of Deep Vein Thrombosis (DVT). This new SCD Express™ system has the potential to provide uninterrupted DVT prophylaxis as it is used throughout the hospital, and it can be worn and used continuously by the patient during the entire period of risk.

The SCD Express™ system has been designed to be more compact, quieter, lightweight, and offer battery power. Additional features also include the ability to provide sequential, gradient compression to each limb individually and the flexibility to provide compression to various sleeves consisting of up to three bladders each.

The SCD Express™ Controller will also have the potential to be used as a compression foot device. A new feature for an SCD-based system, the SCD Express™ Foot Cuff will provide DVT prophylaxis in situations that allow for a wrap only on the foot due to obstacles on the leg (e.g., surgery). In addition, the product has been designed to have the capability of providing high pressure, compression to a foot garment. In this configuration, the SCD Express™ system would still include the controller and a pair of tubing sets, but a pair of single patient use, single bladder disposable foot garments would be used in place of the aforementioned sleeves. The SCD Express™ system will also allow for mixed configurations where a foot garment could be used on one limb while a sleeve was used on the other.

5. Device Intended Use

The SCD Express™ system is designed to apply intermittent pneumatic compression to the lower limbs to help prevent deep vein thrombosis in patients at risk.

Indications for use:
- Circulation Enhancement
- Deep Vein Thrombosis Prophylaxis
- Edema – Acute
- Edema – Chronic
- Extremity Pain Incident to Trauma or Surgery
- Leg Ulcers
- Venous Stasis / Venous Insufficiency

6. Product Comparison

The SCD Express™ Controller and the SCD Response™ Compression System (K992079) as well as the SCD Express™ PCS Foot Cuff to the Novamedix AVImpad (K953648) are substantially equivalent in intended use, function and mode of operation.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2004

Tyco Heathcare/Kendall
c/o Ms. Bridget Gardner
Manager, Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

Re: K040511
Kendall SCD Express™ Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 26, 2004
Received: February 27, 2004

Dear Ms. Gardner:

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 (301) 594-4646. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K040511

Device Name: Kendall SCD Express™ Compression System

Indications For Use:

The SCD EXPRESS*Compression System is designed to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism. The System consists of the Controller, the Tubing Sets (provided with the Controller) and single-patient use garments (purchased separately from this Controller). The garments, both leg sleeves and foot cuffs, compress the limbs to enhance venous blood movement. After the compression, the Controller measures the time it takes for the limbs to refill with blood and waits that period of time before the next compression is initiated.

The use of the SCD EXPRESS Compression System with Foot Cuffs is also indicated for: (a) circulation enhancement, (b) edema – acute, (c) edema – chronic, (d) extremity pain incident to trauma or surgery, (e) leg ulcers, and (f) venous stasis /venous insufficiency.

Prescription Use _√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Bachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040511