DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2006

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

Re: K051805
Kendall SCDTM Sleeves (Large Knee, Large Thigh, Extra Large Knee, Extra Large Thigh)
Kendall SCD Express TM Sleeves (Large Knee, Large Thigh, Extra Large Knee, Extra Large Thigh)
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: II
Product Code: JOW
Dated: September 14, 2005
Received: September 15, 2005

Dear Ms. Gardner:

This letter corrects our substantially equivalent letter of October 13, 2005.

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 (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 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 continue 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 (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 Statement

510(k) Number (if known): K051805

Device Name: **Kendall SCD™ Sleeves (Large Knee, Large Thigh)**
Kendall SCD Express™ Sleeves (Large Knee, Large Thigh)

Indications for Use:

The Kendall SCD™ System is designed to increase venous blood flow in at risk patients, including bariatric and morbidly obese patients, in order to help prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X____ OR Over-The-Counter Use_____ (Per 21 CFR 801.109)

Donna R. Lachman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051805

K 051805

OCT 13 2005

Attachment #7

Summary of Safety and Effectiveness

510(k) Summary

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:

Kendall, a Division of Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048

Date Prepared: July 1, 2005

1. Contact Person

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

2. Name of Medical Device

Proprietary Name:	Sequential Compression Sleeves
Common or Usual Name:	Sleeve, Limb, Compressible
Trade Name:	Kendall SCD™ Sleeves (Extra Large Knee, Extra Large Thigh) Kendall SCD Express™ Sleeves (Extra Large Knee, Extra Large Thigh)

3. Identification of Legally Marketed Device

The proposed devices, Kendall SCD™ and SCD Express™ Sleeves (Extra Large Knee, Extra Large Thigh) are substantially equivalent in intended use, design, function, composition and mode of operation to the currently marketed Kendall Sequential Compression Sleeves (K781357).

4. Device Description

Kendall SCD™ and SCD Express™ Sleeves (Extra Large Knee, Extra Large Thigh) are pneumatic compression devices for applying pressure to a patient's leg for the prevention of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

The SCD™ System is an intermittent pneumatic compression device for applying sequential, gradient pressure to a patient's legs for the prevention of DVT and PE. The SCD™ System consists of a controller, a pair of tubing sets, and a pair of single-patient-use disposable sleeves. The SCD™ product line has been a standard in the mechanical DVT and PE prevention industry.

5. Device Intended Use

The Kendall SCD™ System is designed to increase venous blood flow in at risk patients, including bariatric and morbidly obese patients, in order to help prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

6. Product Comparison

The proposed devices, Kendall SCD™ and SCD Express™ Sleeves (Extra Large Knee, Extra Large Thigh) have the same technological characteristics, intended use, design, function, composition and mode of operation to the currently marketed Kendall Sequential Compression Sleeves (K781357). Both the proposed devices and the predicate devices are intended to be used with an intermittent pneumatic device for applying pressure to a patient's limb for the prevention of deep vein thrombosis.

7. Nonclinical Testing

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