K040649

EXHIBIT # 7

510(k) Summary

JUL 15 2004

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: March 9, 2004

1. Contact Person

Gail Christie
Manager, Scientific Services/Regulatory Affairs
(508) 261-8440

2. Name of Medical Device

Classification Name: Sleeve, Limb, Compressible
Proprietary Name: Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeve

3. Identification of Legally Marketed Device

The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeve, is substantially equivalent in intended use, function and composition to the Kendall T.E.D. Sequential Compression Sleeve (K781357).

4. Device Description

The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeve, is a pneumatic compression device for applying pressure to a patient's leg for the prevention of Deep Vein Thrombosis (DVT). The proposed device is the same composition and design as the currently marketed Kendall T.E.D Sequential Compression Sleeves (K781357) with the additional of a new feature where the thigh length sleeve can be converted to a knee length sleeve. This new design allows the thigh bladder to be removed, leaving a functioning knee length sleeve. The purpose of the *TearAway* function is to allow the clinician to convert the device from a thigh length sleeve to a knee length sleeve without changing to a new sleeve.

The proposed device consists of a pair of single-patient-use poly vinyl chloride (PVC) and nonwoven thigh length sleeves.
The Kendall SCD™ Express™ KAMBIA™,Thigh Length *TearAway* Sleeve is compatible with the Kendall SCD™ 5325 System Controller, the Kendall SCD™ Sequel™ System Controller and the Kendall SCD™ Response™ System Controller.

The controller provides air to the sleeves through tubing connected to each bladder. The controller system monitors the pressure in the bladders and releases the pressure by venting the air from the sleeve bladders through a valve system within the controller.

The thigh-length sleeve is designed to easily convert to a 2-bladder knee-length sleeve by removing the upper bladder at the perforation located between the thigh bladder and the calf bladder. The thigh bladder air supply line is disconnected from the tubing connector at which time a valve activates in the connector, restricting the air flow for the thigh bladder air line.

5. Device Intended Use

The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeve, is intended to be used with an intermittent pneumatic device for applying pressure to a patient's limb to increase blood flow for the prevention of deep vein thrombosis and pulmonary embolism.

6. Product Comparison

The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeves, has the same technological characteristics as the predicate device, Kendall SCD™ Thigh Length Sleeves. Both the proposed device and the predicate device are intended to be used with an SCD™ intermittent pneumatic device for applying pressure to a patient's leg via three bladders located at the thigh, calf and ankle for the prevention of deep vein thrombosis and pulmonary embolism. Both devices are compatible with the Kendall SCD™ 5325 System Controller, the Kendall SCD™ Sequel™ System Controller and the Kendall SCD™ Response™ System Controller.

The construction of both devices consists of sheet material welded together using an RF welding process to create bladders. A tubing port is attached to each bladder, which is used to connect tubing from the sleeve to the controller.

The predicate device, Kendall SCD™ Thigh Length Sleeve, is not able to convert to a knee length sleeve. The predicate device product line consists of a separate knee length sleeve constructed of the same PVC as the thigh length sleeve. The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeve, can be converted to a knee length sleeve using the *TearAway* function. The thigh bladder and tubing are removed leaving a two-bladder knee length SCD™ Sleeve. The predicate device, Kendall SCD™ Knee length sleeve contains a three-bladder system.

Both the thigh and knee length predicate device sleeves have similar pressure profiles as the proposed Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeves.

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

JUL 15 2004

Tyco Healthcare
c/o Ms. Gail Christie
Manager, Scientific Services/Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

Re: K040649
Kendall SCD™ Express™ KAMBIA™ Thigh Length TearAway Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compress Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: May 26, 2004
Received: May 28, 2004

Dear Ms. Christie:

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,

Donna R. Bachner

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): K040649

Device Name: Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeves

Indications for Use:

The proposed device, Kendall SCD™ Express™ KAMBIA™ Thigh Length *TearAway* Sleeves, are intended to be used with an intermittent pneumatic device to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040649