K992079

SEP 2 9 1999

Attachment 4

510 (k) Summary

Summary

Substantial Equivalence Summary for the Kendall Model 7325 SCD Response® Compression System

In accordance with 21 CFR Part 807.92, this summary is submitted by:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date: April 5, 1999

1. Contact Person

Paul W. Evans
Director, Regulatory Affairs
(508) 261-8203

2. Name of the Device

Classification Name:	Compressible Limb Sleeve
Common or Usual Name:	Compressible Limb Sleeve Device
Proprietary Name:	Kendall SCD Response™ Compression System

3. Statement of Substantial Equivalence

The Kendall SCD Response™ Compression System is substantially equivalent to the Kendall SCD Sequel™ Compression System in that the basis of operation for both devices is the inflation of expandable sleeves which in clinical practice are placed around a patient's lower limbs. Inflation of the sleeve is accomplished using air, and a cycle which operates to alternatively inflate and deflate the sleeves at predetermined intervals. The SCD Response™ and the predicate SCD Sequel™ controller are both electrically powered, and are connected to the inflatable sleeves by plastic tubing.

The Kendall SCD Response™ Compression System is substantially equivalent in function, operating parameters, and intended use to the commercially available Kendall SCD Sequel™ Compression System. A significant change between the two systems is that the Response™ system provides the traditional compression sequence of the predicate device with the capability of detecting the patient's venous refill time, and adjusts the decompression cycle to match the user refill time. Over time, this will result in less pooling of blood, and reduce further the potential for deep vein thrombosis (DVT).

4. Description of the Device

The SCD Response™ Compression System is a microprocessor controlled pneumatic compression device which provides intermittent, sequentially graduated pressure to compressible limb sleeves. When the sleeves compress the legs, the veins collapse, forcing the blood to move toward the heart. After compression, the sleeves deflate, allowing the veins to take shape again and fill with blood. The full cycle then repeats again.

5. Intended Use of the Device

The Kendall SCD Response™ Compression System is designed to apply sequential compression to the lower limbs to help prevent deep vein thrombosis (DVT) in patients at risk.

6. Technological Characteristics

The technological characteristics of the SCD Response™ Compression System, e.g., overall design, materials, energy source, mode of operation, performance characteristics, etc. are similar to the predicate Sequel™ Device.

7. Performance Data

Nonclinical Tests – Comparative bench testing of the Kendall SCD Response™ Compression System with the predicate Sequel™ device found similar functional and operational performance characteristics. Such characteristics included compression, pressure control, timing sequence (default cycle), operating alarms, sleeve compatibility, safety, and software testing.

Clinical Tests – No clinical test results were submitted in support of this premarket notification submission.

Test Conclusions – Nonclinical test results of the Kendall SCD Response™ Compression System indicated substantial equivalence to the predicate Sequel™ System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Mr. Paul W. Evans
Director, Regulatory Affairs
Kendall, CO.
15 Hampshire Street
Mansfield, MA 02048

Re: K992079
Kendall Model 7325 SCD Response™ Compression System
Regulatory Class: II (Two)
Product Code: 74 JOW
Dated: August 13, 1999
Received: August 16, 1999

Dear Mr. Evans:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number K992079

Device Name **Kendall Model 7325 SCD Response™ Compression System**

Indications for Use **The SCD RESPONSE Compression System is designed to apply sequential compression to the lower limbs to help prevent deep vein thrombosis in patients at risk.**

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, Respiratory,
and Neurological Devices
510(k) Number K992079

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)