OCT 1 7 2001

K012403
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# 510(k) Summary of Safety & Effectiveness

**Submitter**

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

**Contact**

Mr. Michael Sammon, Ph.D.
Director, Engineering
(863) 683-8680, extension 228
mikes@safe-reuse.com

**Date**

May 31, 2001

**Devices**

- Trade Names: Vanguard Reprocessed Compression Garments
  - ⇒ Kendall SCD™ Sequential Compression Sleeves
  - ⇒ Kendall ImPad™ Rigid Sole Foot Covers
  - ⇒ Huntleigh Healthcare DVT Garments
  - ⇒ Aircast® VenaFlow® Cuffs
  - ⇒ Nutech®PlexiPulse® Wraps
  - ⇒ Healthcare Service & Supply ALP® Alternating Leg Pressure® Garments
- Common Name: Compression garment, Compressible Limb Sleeve
- Classification: 21 CFR 870.5800 – Compressible Limb Sleeve – Class II
- Product Code JOW

**Predicate Devices**

- Kendall SCD™ Sequential Compression Sleeves and ImPad™ Rigid Sole Foot Covers believed to be legally marketed under various possible 510(k) premarket notifications (K781357, K863581, K890938, K932835, K942664, K992079)
- Huntleigh Healthcare DVT Garments believed to be legally marketed under a couple of possible 510(k) premarket notifications (K881632, K961166)
- Aircast® VenaFlow® Cuffs believed to be legally marketed under the possible 510(k) premarket notification K932900
- Nutech®PlexiPulse® Wraps believed to be legally marketed under a couple of possible 510(k) premarket notifications (K944567, K981311)

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# 510(k) Summary of Safety & Effectiveness, Continued

**Predicate Devices,** continued

- Healthcare Service & Supply ALP® Alternating Leg Pressure® Garments believed to be legally marketed under various possible 510(k) premarket notifications (K955853, K964188, K974318, K000303)

**Indications for Use**

When coupled with an appropriate inflation system, compression garments are intended to increase venous return from the legs and feet as a prophylaxis for the formation of deep vein thrombosis (DVT) or subsequent pulmonary embolism (PE) in high risk and/or non-ambulatory patients. The compression garments are prescription devices intended for a single patient use only.

**Device Description**

Compressible limb sleeves are devices that are used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb and increasing venous flow. Compression therapy is generally prescribed as a prophylaxis for deep vein thrombosis (DVT). The compression system consists of two primary pieces: an air compression pump and a soft, flexible sleeve in which the patient's extremity is placed. A hose to the pump connects to the sleeve, and when the pump is turned on, the air inflates the sleeve, applying a gentle pressure to the patient's extremity.

Compression garments consist of a non-woven fabric with "hook and loop" fasteners for attaching around the foot or leg. Air cells within the garment are molded to plastic hoses with connectors for attachment to the pump. The hoses and connectors are non-detachable and are reprocessed as part of the garment. Depending upon the original equipment manufacturer (OEM), garments may contain a single bladder and hose or multiple compartments and hoses that are sequentially pressurized.

Vanguard receives previously used compression garments from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the garments; and returns them to the healthcare facility.

*Continued on next page*

# 510(k) Summary of Safety & Effectiveness, Continued

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|---|---|
| **Technological Characteristics** | The Vanguard reprocessed compression garments are essentially identical to the currently marketed OEM compression garments. No changes are made to the currently marketed devices' specifications (with the exception of sterility) and they possess the same technological characteristics. The OEM devices are marketed as non-sterile. As requested by customers, the Vanguard reprocessed devices are sterilized. Ethylene oxide gas is utilized and the sterilization validation demonstrates that sterility is achieved to a $10^{-6}$ assurance level. Post-sterilization biocompatibility and performance/functional testing also demonstrate that the devices continue to be safe and effective for their intended use. |
| **Test Data** | Decontamination and cleaning, packaging and sterilization validations and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective. |
| **Conclusion** | Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed compression garments are substantially equivalent to the predicate devices, the respective OEM compression garments under the Federal Food, Drug and Cosmetic Act. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 7 2001

Michael Sammon, Ph.D.
Director, Engineering
Vanguard Medical Concepts, Inc.
5307 Great Oaks Drive
Lakeland, FL 33815

Re: K012403
Trade Name: Vanguard Reprocessed Compression Garment
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: May 31, 2001
Received: July 30, 2001

Dear Dr. Sammon:

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.

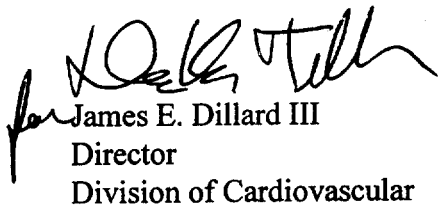
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012403

# Indications for Use

510(k) Number: K012403

Device Name: Vanguard Reprocessed Compression Garments

Indications for Use:

When coupled with an appropriate inflation system, compression garments are intended to increase venous return from the legs and feet as a prophylaxis for the formation of deep vein thrombosis (DVT) or subsequent pulmonary embolism (PE) in high risk and/or non-ambulatory patients. The compression garments are prescription devices intended for a single patient use only.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012403