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510(k) Summary of Safety & Effectiveness

DEC 2 2 2005

Submitter

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

Contact

Trish Stephens
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Date

October 26, 2005

Device

- Trade Name: Vanguard Reprocessed External Fixation Devices
  - Orthofix Radiolucent Wrist Fixator
- Common Name: Reprocessed External Fixation Devices
- Classification: 21 CFR 888.3030
- Classification Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
- Product Code: KTT – Class II

Predicate Devices

External Fixation Devices legally marketed by the following original equipment manufacturer:

Manufacturer	Trade Name
Orthofix, Inc.	Orthofix Radiolucent Wrist Fixator

Indications for Use

Reprocessed External Fixation Devices are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

Contra-indications

- External Fixation Devices are contraindicated in patients with mental or neurologic impairment that would interfere with cooperative postoperative care.
- These devices are not intended for attachment or fixation of screws to the spine.

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510(k) Summary of Safety & Effectiveness, continued

Device Description

Vanguard Reprocessed External Fixation Devices are previously used non-invasive orthopedic devices that have been cleaned, inspected, tested, and packaged by Vanguard Medical Concepts, Inc. External Fixation Device systems are comprised of various elements that, when used in conjunction with one another, form bridge constructs to which anchoring screws, wires and/or pins may be attached. Bridge elements are designed to provide a framework for stabilization of bone fractures where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casting or other means of internal fixation.

External fixation elements consist of components such as straight rods, telescoping rods, rod-to-rod and pin-to-rod couplings and clamps. These components are provided in bulk, packaged in nylon pouches, non-sterile, with instructions for steam sterilization by the health care facility.

Rods and Telescoping Rods ~ Straight rods are external fixation devices of varying lengths (adjustable lengths in the case telescoping rods) and diameters that are used with rod-to-rod and pin-to-rod clamps by the surgeon to connect anchoring pins and screws together to form a rigid structure that immobilizes the affected bone or structures. Differences in length and diameter of the rods allow accommodation of a broad range of fracture scenarios and applied loads. All rods have a straight, solid, round design. Rods and telescoping rods are typically constructed of stainless steel, carbon fiber, or aluminum or a combination of materials.

Rod-to-Rod Couplings or Clamps ~ Rod-to-rod couplings or clamps are multi-element components used to connect one rod to another in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods. The devices are typically constructed from one or more of the following materials: anodized aluminum alloys, steel or stainless steel alloys and titanium alloys.

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510(k) Summary of Safety & Effectiveness, continued

Device Description (continued)

Rod-to-Pin Couplings or Clamps ~ These are multi-element components used to connect one rod or tube to a pin or group of pins in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods or tubes to specific sizes or ranges of sizes of pins. The devices are typically constructed from one or more of the following materials: anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.

Technological Characteristics

Vanguard Reprocessed External Fixation Devices are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the currently marketed OEM device specifications and the Reprocessed External Fixation Devices possess identical technological characteristics.

Test Data

Cleaning, packaging, and performance testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed External Fixation Devices are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Ms. Trish Stephens
Project Manager, Research & Development
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K053051
Trade/Device Name: Vanguard Reprocessed External Fixation Devices
(See enclosed list)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: October 26, 2005
Received: October 28, 2005

Dear Ms. Stephens:

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 (240) 276-0210. 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed External Fixation Device Models found to be **Substantially Equivalent**:

OEM	Catalog #	Description
Orthofix	3600A	Radiolucent Wrist Fixator Body
	36008	Distraction Module
	36017	Allen Wrench, 4mm
	13620	Drill Guide
	13621	Screw Guide
	M210	T-Wrench

K053051

Indications for Use

510(k) Number (if known): K053051

Device Name: Vanguard Reprocessed External Fixation Devices

Indications for Use:

Reprocessed External Fixation Devices are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(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 General, Restorative, and Neurological Devices

510(k) Number K053051