510(k) Summary of Safety & Effectiveness

K043594

MAR 3 1 2005

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Submitter

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

Contact

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Director of Regulatory Affairs
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Date

December 28, 2004

Device

- Trade Name: Vanguard Reprocessed Bladed and Non-Bladed Trocars (US Surgical/AutoSuture Series)
- Common Name: Bladed and Non-Bladed Trocar
- Classification Number: 21 CFR 876.1500
- Classification Name: Endoscope and accessories
- Product Code: NLM – Laparoscope, General & Plastic Surgery, Reprocessed – Class II

Predicate Devices

Original equipment manufacturer (OEM) Bladed and Non-Bladed Trocars are currently marketed under a variety of trade names. Trade names of current legally marketed predicate devices are:

- US Surgical (AutoSuture) VersaPort™ V2 (5-12mm) Trocar System
- US Surgical (AutoSuture) VersaPort™ RPF (5-12mm) Trocar System
- US Surgical (AutoSuture) VersaPort™ RT (5-12mm) Trocar System
- US Surgical (AutoSuture) BluntPort™ (5-12mm) Trocar System
- US Surgical (AutoSuture) VersaStep™ (5-12mm) Trocar System
- US Surgical (AutoSuture) SpringGrip Anchoring Accessory

The 510(k) Premarket Notification numbers for these devices are:

- K012539: VersaStep
- K963115: Trocar Cannula
- K954108: Modified VersaPort
- K945457: Trocar (Accessory)
- K931337: AutoSuture Dilating Cannula

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510(k) Summary of Safety & Effectiveness, Continued

Indications for Use

Reprocessed trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological, and thoracic procedures.

Contra-indications

Reprocessed trocars should not be used in patients for whom endoscopic procedure is contraindicated.

Device Description

A Vanguard Reprocessed Trocar is a previously used device that has been cleaned, inspected, packaged and sterilized by Vanguard Medical Concepts, Inc.

Trocar Cannulae are available in sizes 5-15mm inner diameter and 70-100mm length. Cannulae are equipped with a pressure seal for maintenance of pneumopertineum during insertion and withdrawal of instruments. Some models are equipped with a luer stopcock port for insufflation and desufflation of the operative cavity. Some models are provided with stability anchors inserted over the cannula sleeve to help seal the incision site and maintain cavity pressure.

Trocar Obturator is available in bladed and non-bladed configurations sized 5-15mm. Bladed models are equipped with a safety shield designed to expose the blade during insertion but to retract over the tip once the operative cavity has been penetrated so as to reduce the risk for vascular or visceral injury.

Non-Bladed obturators have either a rounded (blunt) tip or sharply tapered (dilator) tip to allow trocar insertion following a cut down and minimize the risk for internal injury.

Vanguard receives previously used trocars from healthcare facilities; cleans, inspects, tests, packages, labels, and sterilizes the devices; and returns them to a healthcare facility for subsequent use.

Technological Characteristics

Vanguard Reprocessed Bladed and Non-Bladed Trocars are essentially identical to the Original Equipment Manufacturer (i.e., AutoSuture®) devices. No changes are made to the device materials or specifications and the reprocessed trocars possess identical technological characteristics.

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Test Data

Cleaning, sterilization, packaging validations, and performance and biocompatibility 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 Bladed and Non-Bladed Trocars are substantially equivalent to their legally marketed predicate devices 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

NOV 27 2006

Ascent Healthcare Solutions
% Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, Arizona 85044

Re: K043594 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CRF 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: March 7, 2005
Received: March 9, 2005

Dear Ms. Barton:

This letter corrects our substantially equivalent letter of March 31, 2005. The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on March 31, 2005. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices in the Federal Register.

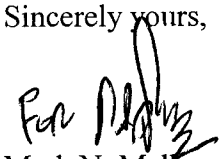
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K043594

Device Name: Vanguard Reprocessed Bladed and Non-Bladed Trocars

Indications For Use:

Reprocessed trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological, and thoracic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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, Restora[illegible]
and Neurological Devices

510(k) Number K043594

List of Models:

US Surgical (AutoSuture)VersaPort™ V2 (5-12 mm) Trocar System
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