K012700

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JUL 2 9 2005

510(k) Summary of Safety & Effectiveness

Submitter

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

Contact

Heather Crawford, RAC
Director, Regulatory Affairs
(863) 683-8680 (voice)
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hcrawford@safe-reuse.com

Date

June 08, 2005

Device

- Trade Names: Vanguard Reprocessed Electrosurgical Instruments
- Common Name: Endoscopic surgical instruments, laparoscopic surgical instruments
- Classification: 21 CFR 876.1500 – Endoscope and accessories – Class II
- Product Code: GCJ

Predicate Devices

Respective Ethicon Endo-Surgery ENDOPATH® and AutoSuture® endoscopic instruments legally marketed under various 510(k) premarket notifications.

Indications for Use

Dissector instruments are used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for grasping, mobilization, dissection and/or cauterization of tissue.

Scissor instruments are used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for mobilization, transection and/or cauterization of tissue.

Contra-indications

This device is not intended for contraceptive coagulation of fallopian tissue or applications where minimally invasive surgery is contraindicated.

Continued on next page

ENDOPATH is a registered trademark of Ethicon Endo-Surgery, Inc., a Johnson & Johnson company
AutoSuture is a registered trademark of United States Surgical, a division of Tyco Healthgroup LP

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510(k) Summary of Safety & Effectiveness, Continued

Device Description

The electrosurgical instrument is used for grasping, dissection and cauterization in endoscopic general surgery. The distal instrument scissors or jaws are opened and closed using ring loop handles. The instrument shaft is insulated and designed for use with an appropriately sized trocar cannula; the shaft can be rotated 360° in either direction using a handle knob. Devices with electrocautery capability are supplied with a pin for connection to a compatible electrosurgical unit; use of the device for monopolar electrocautery requires use of a patient grounding pad. Monopolar electrocautery is possible only with instruments equipped with a cautery pin in conjunction with a compatible electrosurgical unit and patient grounding pad.

Vanguard receives previously used electrosurgical instruments from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to a healthcare facility.

Technological Characteristics

Vanguard reprocessed electrosurgical instruments are essentially identical to the currently marketed Original Equipment Manufacturer (OEM) devices. Device materials, specifications, and technological characteristics are equivalent.

Test Data

Cleaning, sterilization, and packaging validations, and performance and biocompatibility testing demonstrate 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 electrosurgical instruments are substantially equivalent to their 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

JUL 29 2005

Ms. Heather Crawford, RAC
Director, Regulatory Affairs
Vanguard Medical Concepts Inc.
5307 Great Oak Drivce
Lakeland, Florida 33815-3113

Re: K012700
Trade/Device Name: Vanguard Reprocessed Electrosurgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: April 21, 2005
Received: April 22, 2005

Dear Ms. Crawford:

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) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

The Original Equipment Manufacturers (OEMs) and device models in this SVS application K012700 are:

OEM	Model#	Diameter	Length	Description
Ethicon w/unipolar cautery	5DCD	5mm	32cm	Curved Dissector
Ethicon w/unipolar cautery	5DCS	5mm	32cm	Curved Scissors
US Surgical Mini-Shears cautery	174301	5mm	32.5cm	AutoSuture Endo w/unipolar
US Surgical Shears w/unipolar cautery	176643	5mm	33cm	AutoSuture Endo
US Surgical Dissector Shears cautery	176645	5mm	33cm	AutoSuture Endo w/unipolar

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K012700

Indications for Use

510(k) Number (if known): K012700

Device Name: Vanguard Reprocessed Electrosurgical Instruments

Indications for Use:

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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 K012700