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K042594
Page 1 of 2

510(k) Summary of Safety & Effectiveness

Submitter

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

Contact

Heather Crawford, RAC
Director of Regulatory Affairs
863-683-8680 [voice]
863-683-8703 [facsimile]
hcrawford@safe-reuse.com [email]

Date

September 23, 2004

Device

- Trade Name: Vanguard Reprocessed Non-Electric Biopsy Forceps
- Common Name: Reprocessed Non-Electric Biopsy Forceps
- Classification: 21 CFR, 876.1075(b)(2) – Forceps, Biopsy, Non-Electric, Reprocessed – Class I
- Product Code: NON

Predicate Devices

- Trade Names:
  - Bard Precisor™ XL Coated non-electric biopsy forceps
  - Microvasive® MultiBite® non-electric biopsy forceps
  - Microvasive® Radial Jaw® non-electric biopsy forceps
  - Microvasive® Radial Jaw® 3 non-electric biopsy forceps
  - Microvasive® Radial Jaw® Large Capacity non-electric biopsy forceps
  - Microvasive® Radial Jaw® 3 Max Capacity non-electric biopsy forceps
  - Wilson Cook Medical The Shark™ non-electric biopsy forceps
- 510(k) numbers: Not applicable

Original equipment manufacturer (OEM) non-electric GI biopsy forceps are Class I 510(k) exempt devices (21 CFR 876.1075, product code FCL). Therefore premarket notifications for the legally marketed predicate devices are not applicable for citation.

Continued on next page

Microvasive, MultiBite and Radial Jaw are registered trademarks of Boston Scientific Corporation
Precisor is a trademark of C.R. Bard, Inc.
The Shark is a trademark of Wilson-Cook Medical GI Endoscopy

510(k) Summary of Safety & Effectiveness, Continued

Indications for Use

GI forceps are designed for insertion through an appropriate sized endoscopy channel for removal and histological sampling of tissue. Biopsy forceps are intended for removal of polyps and/or tissue within the gastrointestinal tract.

Contra-indications

This GI biopsy forceps should not be used:

- for pulmonary biopsy procedures;
- when contraindications to GI endoscopy are present, e.g. acute abdominal peritonitis, toxic megacolon, or active colitis;
- in the possible presence of combustible gases (e.g. anesthetic);
- in patients with bleeding disorders; or
- in a side viewing endoscope.

Device Description

Vanguard Reprocessed Non-Electric Biopsy Forceps consist of a flexible sheath with distal grasping cups controlled by a proximal control handle. When used with a compatible endoscope, GI biopsy forceps are intended for removal of polyps and/or tissue within the gastrointestinal tract. Biopsy forceps are designed for insertion through a predetermined diameter biopsy channel.

Vanguard receives previously used non-electric GI biopsy forceps 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 Non-Electric Biopsy Forceps are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the device materials or specifications and the reprocessed forceps possess identical technological characteristics.

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 Non-Electric Biopsy Forceps 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

JAN 25 2005

Vanguard Medical Concepts, Inc
c/o Ms. Heather Crawford
5307 Great Oak Drive
LAKELAND FL 33815

RE: K042594
Trade/Device Name: Vanguard Reprocessed
Non-electric Biopsy Forceps
(Enclosure 1)
Regulation Number: 21 CFR § 876.1075
Regulation Name: Gastroenterology-urology
Biopsy instrument
Regulatory Class: II
Product Code: 78 NON
Dated: December 21, 2004
Received: December 22, 2004

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 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.

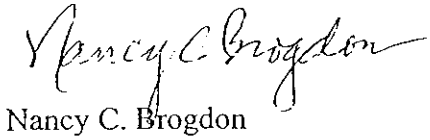
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042594

Indications for Use

510(k) Number (if known): K042594

Device Name: Vanguard Reprocessed Non-Electric Forceps

Indications For Use: GI forceps are designed for insertion through an appropriate sized endoscopy channel for removal and histological sampling of tissue. Biopsy forceps are intended for removal of polyps and/or tissue within the gastrointestinal tract.

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)

David A. Krym

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042594