510(k) Summary of Safety & Effectiveness

K053585

Submitter

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

OCT 11 2006

Contact

Trish Stephens
R&D Project Manager
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Date

December 22, 2005

Device

- Trade Name: Vanguard Reprocessed Suture Passer
- Common Name: Suture Passer, Carter-Thomason Needle-Point Suture Passer
- Classification Name: Laparoscope, General & Plastic Surgery, Reprocessed
- 21 CFR Section: 876.1500
- Reprocessed – Class II
- Product Code: NLM

Predicate Devices

- Trade Names:
  - Inlet Medical, Inc. CloseSure® Procedure Kit
- 510(k) numbers:
  - K980123: Louisville Laboratories, Inc. (Inlet Medical, Inc.) Carter-Thomason Needle-Point Suture Passer Instrument Kit

Indications for Use

Reprocessed Suture Passers are intended to pass sutures through soft tissue during endoscopic/laparoscopic surgery.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

The Reprocessed Suture Passer is a set of previously used devices that have been cleaned, tested, inspected, marked with an identifier, packaged, labeled, and sterilized by Vanguard. A "Suture Passer" is a set of three (3) devices, consisting of one (1) Carter-Thomason needle-point suture passer and two (2) suture passer guides. The Carter-Thomason needle-point suture passer is a 3mm diameter stainless steel shaft with a polycarbonate ring-grip handle that opens one side of the pointed tip of the steel shaft when activated. The polycarbonate suture passer guides have a cylindrical hub at the proximal end and a tapered shaft at the distal end. The suture passer guides taper from the junction with the cylindrical hub to the tip. Each suture passer guide has two holes in the hub; the two holes open on opposite sides of the pilot guide shaft.

A Suture Passer Guide is inserted into the wound site. A Suture Passer is used to push suture through the suture passer guide and then through the tissue of the wound site. The suture is then retrieved and pulled through the opposite side of the guide. This creates a "loop" that encompasses the full depth of the wound and upon removal of the guide allows full closure of the wound.

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

Technological Characteristics

The Vanguard Reprocessed Suture Passers 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 upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Suture Passers 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

OCT 11 2006

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

Re: K053585 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: January 12, 1998
Received: January 14, 1998

Dear Ms. Barton:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on March 9, 1998. 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

Device listing found to be substantially equivalent:

Carter-Thomason CloseSure System
(1) Carter-Thomason Need-Point Suture Passer
(1) 5mm Suture Passer
(1) 10/12mm Suture Passer Guide

Indications for Use

510(k) Number (if known): K053585

Device Name: Vanguard Reprocessed Suture Passers

Indications for Use:

Reprocessed Suture Passers are intended to pass sutures through soft tissue during endoscopic/laparoscopic 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 K053585