

DEC 18 2003

K032980

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# ***Vanguard Medical***

5307 Great Oak Drive  
Lakeland, FL

Tel: (863) 683-8680  
Fax: (413) 215-9809

## **510(k) SUMMARY**

Reference: Vanguard Medical Concepts, Inc.  
Section 510(k) Notification  
AMI Reprocessed Multiple Clip Appliers (Non Re-loadable)

Classification name: LSR Disposable Stapler  
Manual Surgical Instrument

Common/Usual Name: Disposable Surgical Instruments

Proprietary Name: Vanguard Reprocessed Multiple Clip Appliers

Establishment Reg. No.: 1649663

Classification: The FDA has classified Manual, General Surgical  
Instruments as Class I devices under the General and  
Plastic Surgery Panel (21 CFR 878.4800)  
As an implantable clip, Class II.

Vanguard Medical Concepts, Inc., intends to market Reprocessed Disposable, Multiple Clip Appliers with non changeable reloads. Reprocessing Multiple Clip Appliers is performed by Vanguard to Vanguard Potocol Number 40017.

"Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*). Vanguard is a "third party reprocessor" and reprocesses used single-used medical devices.

Appliers are sold new by the original manufacturers to the hospital. The hospital uses the appliers, collects them and ships them to Vanguard for reprocessing. Appliers are reprocessed by Vanguard as described in our reprocessing protocol Control Document Number 40017, and returns them to the hospital to be reused as a single-use device again.

Vanguard believes that single-use Appliers can be considered "reusable" - by Vanguard" as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

Vanguard reprocessed appliers are substantially equivalent to Ethicon disposable surgical and endoscopic Ligaclip Multiple Clip Appliers currently marketed new by Ethicon under 510(k) 830503.



DEC 18 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vanguard Medical Concepts, Inc.  
c/o Mr. Mark W. Aldana  
Adven Medical, Inc.  
3706 76<sup>th</sup> Street  
Lubbock, Texas 79423

Re: K032980

Trade/Device Name: Reprocessed Multiple Clip Appliers  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable clip  
Regulatory Class: II  
Product Code: FZP  
Dated: September 22, 2003  
Received: October 3, 2003

Dear Mr. Aldana:

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 (301) 594-4659. 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/dsma/dsmamain.html>

Sincerely yours,



*for* Celia M. Witten, Ph.D., M.D.  
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): K032980

Device Name: Reprocessed Multiple Clip Appliers

Indications For Use:

Multiple clip appliers are indicated for ligation of tubular structures.

Vanguard intends to reprocess multiple clip appliers one time.

Reprocessed multiple clip appliers are single use devices.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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