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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]
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hcrawford@safe-reuse.com [email]

Date

April 20, 2005

Device

- Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
- Common Name:
  - → Reprocessed Diagnostic Electrophysiology Catheter
  - → Electrode Recording Catheter
  - → Diagnostic Electrophysiology (EP) Catheter
- 21 CFR Section: 870.1220
- Classification Name: Catheter, Electrode Recording, or Probe, Electrode Recording
- Product Code: NLH – Class II

Predicate Devices

- Trade Name:
  - EP Technologies EPT-Dx™
- 510(k) number:
  - K940168: EP Technologies, Inc., Diagnostic II Catheter

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510(k) Summary of Safety & Effectiveness, Continued

Indications for Use

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g., evaluation of arrhythmias or cardiac mapping.

Contra-indications

- Patients with active systemic infection.
- Patients with prosthetic valves.
- Retrograde approach in patients with aortic valve replacement.
- Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- Patients with acute factors that make the findings unrepresentative of the patient's usual state (i.e. drug toxicity, electrolyte abnormality, acute ischemia).
- Patients with underlying cardiac disease that increases risk of being unable to terminate induced arrhythmias and that have a high risk of death (i.e. unstable angina, acute myocardial infarction, hemodynamic instability).
- Diagnostic EP catheters are not intended for electrical ablation.

Device Description

Vanguard reprocessed diagnostic electrophysiology catheters are constructed of a hollow polymer shaft 6 French in diameter and 110 cm in length that terminates with a hand piece. Various configurations of distal platinum alloy electrodes are wired to a proximal connector at the end of the hand piece for bi-directional transmission of electrical signals (pacing and recording). The proximal connector is attached to an interconnecting cable that interfaces with various standard types of sensing, recording, stimulation, and pacing equipment. The distal tip segment of the catheter is capable of unidirectional steering through manipulation of the hand piece. This remote manipulation of the distal tip segment facilitates precise positioning of the electrode array. The catheters are available in a variety of electrode configurations that are selected by the clinician based on preference and/or indication. The shaft polymer is manufactured with additives (typically barium sulfate) that enhance the catheter's radiopacity to enable positioning under fluoroscopic guidance. No lumens of the catheters reprocessed by Vanguard are open to the patient bloodstream.

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510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	The Vanguard Reprocessed Diagnostic Electrophysiology Catheters 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 Diagnostic Electrophysiology Catheters 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

JUN 6 - 2005

Vanguard Medical Concepts, Inc.
c/o Ms. Heather Crawford, RAC
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

Re: K051043
Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
(See Enclosed List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: April 25, 2005
Received: April 25, 2005

Dear Ms. Crawford:

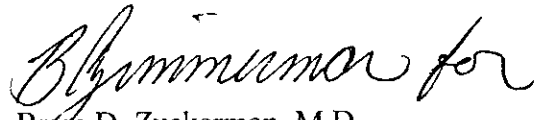
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Model numbers

Models found SE:
EPT-Dx
1103
1101
1102
1300
1301

Indications for Use

510(k) Number (if known): K051043

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheter

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g., evaluation of arrhythmias or cardiac mapping.

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 Cardiovascular Devices
510(k) Number K051043