K030005

510(k) Summary of Safety & Effectiveness

MAR 1 8 2003

Submitter	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
Contact	Mike Sammon, Ph.D. Director, Research and Development (863) 904-1628 (801) 327-3339 (facsimile) msammon@safe-reuse.com
Date	December 31, 2002
Device	• Trade Names: Vanguard Reprocessed Electrophysiology (EP) Catheter Accessory Cable • Common Name: Electrode Cable • Classification: 21 CFR 870.2900 – Class II – Cable, Transducer and Electrode, Patient, (including connector) • Product Code DSA
Predicate Devices	• Biosense Webster EP Catheter Accessory Cables (unknown) • Daig™ EP Catheter Accessory Cables (K910645) • Medtronic EP Catheter Accessory Cables (K894981, K882174)
Indications for Use	Electrophysiology catheter accessory cables are intended for use during electrophysiology studies to connect an electrode catheter to recording/pacing equipment.
Contra-indications	None known

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510(k) Summary of Safety & Effectiveness, Continued

Device Description

Vanguard reprocessed electrophysiology catheter accessory cables are accessories to an appropriate diagnostic catheter. The use of the cable provides a means of electrically connecting the EP catheter to recording/pacing equipment while allowing the catheter to remain in the sterile field and also provides additional working length.

Vanguard reprocessed accessory cables are constructed of a hollow polymer shaft approximately 4 to 7 feet in length that terminates with at each end with a connector. One connector couples with the proximal connector of an electrophysiology catheter; the other connector couples with an extension cable or an electrophysiology console. Various connector types are available at each end to match the appropriate electrophysiology catheter and console.

Vanguard receives previously used accessory cables from healthcare facilities and cleans, inspects, tests, applies a unique serial number, packages, labels, and sterilizes each device for return to the healthcare facility.

Technological Characteristics

Vanguard Reprocessed EP Catheter Accessory Cables are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the device materials or specifications and the reprocessed catheters possess identical technological characteristics.

Test Data

Cleaning, sterilization, and packaging validations and performance 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 EP Catheter Accessory Cables 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

MAR 1 8 2003

Vanguard Medical Concepts, Inc.
c/o Dr. Mike Sammon, Ph.D.
Director, Research and Development
5307 Great Oak Drive
Lakeland, FL 33815

Re: K030005
Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheter Accessory Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Cable, Transducer and Electrode, Patient, (including connector)
Regulatory Class: Class II (two)
Product Code: DSA
Dated: December 31, 2002
Received: January 2, 2003

Dear Dr. Sammon:

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) 594-4646. 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" (21CFR Part 807.97) you may obtain. 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,

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

Enclosure

Indications for Use

510(k) Number: K030005

Device Name: Vanguard Reprocessed Electrophysiology Catheter Accessory Cables

Indications for Use:

Electrophysiology catheter accessory cables are intended for use during electrophysiology studies to connect an electrode catheter to recording/pacing equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number