K040751

MAR 1 0 2005

510(k) Summary

Classification Name

Common/Usual Name: Diagnostic electrophysiological catheter

Proprietary Name: *T20* Diagnostic Deflectable Tip Catheter

Name of Predicate Device

Cordis Webster Diagnostic 7F Deflectable Tip Catheter (primary)
Cordis Webster Orthogonal Catheter (secondary)

Device Description

The Cordis Webster deflectable *T20* electrode catheter has been designed for electrophysiological mapping of the tricuspid annulus. The catheter has a high-torque shaft with a halo-shaped tip section containing ten pairs of platinum electrodes that can easily be seen under fluoroscopy. The tip section also contains a radiopaque marker in the center of the electrode array. The tip section of the catheter has a halo-shaped preformed loop which can be positioned around the atrial aspect of the tricuspid annulus.

A piston in the handpiece is attached to an internal puller which changes the radius of curvature. When the piston is pushed forward, the radius of curvature of the preformed loop is reduced; when the thumbknob is pulled back, the radius of curvature is increased until the tip section returns to the preformed shape. The high-torque shaft allows the plane of the loop to be maneuvered in order to facilitate accurate positioning.

The Cordis Webster deflectable *T20* electrode catheter facilitates simultaneously local electrograms spanning the tricuspid annulus, from midseptal to anterior to lateral to posterolateral. Recordings of the entire annulus can be obtained without repositioning the catheter tip.

Intended Use

The Cordis Webster deflectable *T20* electrode catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The preformed shape of the tip section is designed specifically for the tricuspid annulus.

510(k) Summary (Continued)

Technological Characteristics

The subject device is technologically similar to the predicate device, the Cordis Webster Diagnostic Deflectable catheter. The design of the *T20* electrode catheter, the subject device, includes a greater number of ring electrodes, 20, as compared to the Cordis Webster Diagnostic Deflectable catheter which has 4 and the Cordis Webster Orthogonal catheter which has 12 poles. The nominal width of each ring electrode used in the *T20* is 0.7mm compared to 1.3mm for the standard deflectable catheter. The distal tip of the *T20* electrode catheter has a "halo" shape as compared to A - F curve availability for distal tip deflection of the standard deflectable catheter. The differences indicated do not affect the safety or effectiveness of the device.

Performance Data (Nonclinical Testing)

The nonclinical performance testing performed on the *T20* electrode catheter compared to the predicate device indicated that there were no statistically significant differences in the outcome of the tests for each of the devices that would affect the safety and effectiveness of the device. The tests on the following table were performed according to FDA's "Electrode Recording Catheter Preliminary Guidance". Certain tests were not applicable to this device and justifications are given for the absence of those particular tests.

Conclusions Drawn from the Nonclinical Tests

The results of the nonclinical performance tests indicate that the *T20* electrode catheter performs as well as the predicate device (the standard Cordis Webster Diagnostic 7F Deflectable Catheter) and that the differences in testing outcome are not statistically significant; therefore, Cordis Webster concludes that the *T20* catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2005

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

Re: K040751
Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
(see enclosed list)
Regulation Number: 21 CFR 870.1220
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: NLH
Dated: December 28, 2004
Received: December 29, 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 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 Models:

Halo XP – 7F Diameter, 110 cm long, 20 electrodes, Tricuspid/Halo XP Curve		
Catalog Number	Electrode Spacing	Connector Type
D7-T20-P15-FS	2-13-2mm (no tip electrode)	15-pin molded (2)
D7-T20-P15-RT	2-13-2mm (no tip electrode)	10-pin Redel (2)
D7-T20-282-FS	2-8-2mm w/20mm leader (no tip electrode)	15-pin molded (2)
D7-T20-282-RT	2-8-2mm w/20mm leader (no tip electrode)	10-pin Redel (2)

Indications for Use

510(k) Number (if known): K040751

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping. In addition, the preformed shape of the Halo XP catheter's tip section is designed particularly for the tricuspid annulus.

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 K040751