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SECTION 4 - 510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) number: K080364

Date Prepared: AUG 12 2008
February 06, 2008

Applicant Information:
SentreHEART
2468 Embarcadero Way
Palo Alto, CA 94303

Contact Person:
Linda Guthrie, Manager Regulatory Affairs
Phone Number: (650) 354-1200 x105
Fax Number: (650) 354-1204

Device Information:

Trade Name:	FindrWIRZ Guide Wire System
Classification:	Class II per 21CFR 870.1330
Classification Name:	Wire, Guide, Catheter
Product Code:	DQX

Physical Description:
The FindrWIRZ System consists of the following components:
A 0.035" x 90 cm FindrWIRZ
A 0.025" x 260 cm FindrWIRZ
Guide wire introducer
Torque device

Each FindrWIRZ is configured with a tapered core wire and a distal coil, the 0.035 FindrWIRZ has a proximal PTFE jacket and both wires have a hydrophilic coating. The distal tip of each wire has an encapsulated magnet of opposite polarization which is used for proximity sensing and connection of the two guide wires to facilitate manipulation and positioning of each other. The FindrWIRZ System is sterilized with 100% ethylene oxide.

Intended Use:
The FindrWIRZ System is intended for use in the cardiovascular system for introduction and positioning of over-the-wire catheters and therapeutic devices during interventional procedures. A FindrWIRZ may also be used to manipulate and or reposition another FindrWIRZ.

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The FindrWIRZ System is not intended for use in the coronary or cerebral vasculature. FindrWIRZ are not intended for use in crossing chronic total occlusions.

Contraindications: The FindrWIRZ system is contraindicated for use with rotational atherectomy devices, ferromagnetic interventional devices and Inferior Vena Cava (IVC) filters. The FindrWIRZ system is also contraindicated for use in MRI procedures.

Predicate Devices:
OnTrac, Lake Region (K914138)
Cronus Wire, Stereotaxis (K042854)
Radius Snare Device, Radius Medical Technologies (K071457)

Safety and Performance:
Performance
Functional testing was conducted to support the claim of substantial equivalence and to demonstrate the FindrWIRZ Guide Wire System is safe and effective for its intended use.

Biocompatibility
The materials used in the FindrWIRZ Guide Wire System are commonly used materials in other medical devices. Results of testing demonstrate the FindrWIRZ Guide Wire System is biocompatible.

Summary:
Based on the intended use, product testing, and information provided in this notification, the subject device has been shown to be safe and effective for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2008

Sentreheart Inc.
c/o Ms. Linda Guthrie
2460 Embarcadero Way
Palo Alto, CA 94303

Re: K080364
Trade/Device Name: FindrWirz Guidewire System
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: July 16, 2008
Received: July 18, 2008

Dear Ms. Guthrie:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 3 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080364

Device Name: FindrWIRZ Guide Wire System

Indications for Use: The FindrWIRZ System is intended for use in the cardiovascular system for introduction and positioning of over-the-wire catheters and therapeutic devices during interventional procedures. A FindrWIRZ may also be used to manipulate and or reposition another FindrWIRZ.

The FindrWIRZ System is not intended for use in the coronary or cerebral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080364