5. 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

JAN 2 8 2010

510(k) Summary

510(k) Number: K093822

Date Prepared August 26, 2009

Submitter Information

Submitter's Name/Address: Shepherd Scientific, Inc.
1515 Coast Walk
La Jolla, CA 92037

Establishment Registration: TBA

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President
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Device Information

Trade Name: AngioAssist
Common Name: Catheter Guide Wire Accessory
Classification Name: Wire, Guide, Catheter
Product Code: DQX
Regulation: Class II, 21 CFR 870.1330
Panel: Cardiovascular

Performance Standards

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Device	Manufacturer	510(k) Status
Cinch QR Steerable Guidewire Extension Accessories	Cordis Corporation	K963171
Ostial Pro Stent Positioning System	Ostial Solutions, LLC	K062192
Torque Device	Merit Medical Systems, Inc.	K072552
WireClip Torquer	Boston Scientific	K003398
KEEP Accessory Organizer	Merit Medical Systems, Inc.	Exempt

5.1. Device Description

The AngioAssist consists of the Docking Station , Teirstein Edge and AngioAssist Combination Device. The devices are provided sterile for single use.

5.2. Intended Use/Indications for Use

The AngioAssist is a set of manual instruments intended to facilitate alignment and introduction of interventional devices (i.e., guide wires and catheters) within the coronary and peripheral vasculature.

5.3. Summary of Non-Clinical Testing

The AngioAssist instruments underwent performance and biocompatibility testing to verify that the device functions in a safe and effective manner. The results of the tests provide reasonable assurance that the devices have been designed and tested to assure conformance to the requirements for the indications for use.

5.4. Statement of Equivalence

The AngioAssist instruments are substantially equivalent to the predicate devices listed above based on a comparison of the indications for use and the technological characteristics. The testing performed confirms that the AngioAssist will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 28 2010

Shepherd Scientific, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K093822
Trade/Device Name: AngioAssist Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire Accessory
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 31, 2009
Received: January 6, 2010

Dear Mr. Job:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

The Indications for Use Statement is provided on the following page.

Indications for Use Statement

510(k) Number (if known): K093822

Device Name: AngioAssist

Indications for Use:

The AngioAssist is a set of manual instruments intended to facilitate alignment and introduction of interventional devices (i.e., guide wires and catheters) within the coronary and peripheral vasculature.

Prescription Use ✓ (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)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

510(k) Number K093822