SeerCare™
Lifetech Scientific

FEB 14 2011

Exhibit #6 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The 510(k) Number is K100184

Date of Submission: 02 SEPT 2010

Sponsor:
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Proposed Device **FuStar™ Steerable Introducers**

Classification:
Class II
Product Code: DQY
Classification Name: catheter, percutaneous
Regulation Number: 21 CFR 870.1250
Review Panel: Cardiovascular

Predicate Device:
Predicate Device 1:
510(k) Number: K072313
Trade Name: AMPLATZER Torqvue Delivery System
Manufacturer: AGA Medical Corporation

Predicate Device 2:
510(k) Number: K061119
Trade Name: Enpath Medical Steerable Sheath
Manufacturer: Enpath Medical Inc

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Intended Use: FuStarTM Steerable Introducer is indicated to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Device Description: The FuStarTM Steerable Introducers are designed to perform as a guiding sheath and/or introducer sheath, which provides a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature. Its low-profile design and atraumatic tip reduce the potential risk for trauma during percutaneous punctures while facilitating passage of a wide variety of catheters and devices.

The proposed introducer can give physicians good control during operation, the curl options are available at 30mm (Small) and 50mm (Large). In each option, there are 2 connector types which are luer lock connector and silicone valve connector, and several specifications combination. Also, the visible knob with scale of controller facilitates the physicians to estimate the deflecting angle of the sheath while intra-operation.

The products are available in different effective length (550mm, 700mm and 900mm) and diameter (French size, 5F, 6F, 7F, 8F, 9F and 10F). The deflectable angle of sheath is from 0 degree to 180 degree.

Testing Conclusion: Performance testing was conducted to validate and verify that the proposed device met all design specifications including:

Performance Test: Primary Dimension Test; Exterior Surface Condition X-Ray Visible Testing; Bending Test, Cycle (Fatigue) Test: Conical Fitting Test: Hub Test; Connection Strength Test: Corrosion Resistance test, Leakage and Aspiration Test.
Biocompatibility Test: Cytotoxicity, Acute Systemic Toxicity, Intracutaneous Reactivity Test, Hypersensitivity Test, Hemolysis Test, Complement System Test, Thrombosis Test
Sterilization: Sterilization Validation, Package Integrity Test, Pyrogen Test and Endotoxicity Test.

SE Conclusion: FuStar™ Steerable Introducers, can be claimed to be Substantially Equivalent (SE) to the predicate device, Predicate Device AMPLATZER Torqvue Delivery System K072313 and Enpath Medical Steerable Sheath, K061119.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lifetech Scientific (Shenzhen) Co., Ltd
C/O Ms. Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, No.19, Lane 999, Zhongshan Road (S-2),
Shanghai, 200030, China

FEB 14 2011

Re: K100184
Trade/Device Name: FuStar™ Steerable Introducers
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 18, 2011
Received: January 19, 2011

Dear Ms. Hong:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 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

SeerCare™
Lifetech Scientific

Section II Indication for Use Statement

510(k) Number: K100184

Device Name: FuStar™ Steerable Introducers

Indications for Use:

FuStar™ Steerable Introducer is indicated to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100184