K102484

NOV - 9 2010

先健科技(深圳)有限公司
Lifetech Scientific (Shen Zhen) Co., Ltd

Section III 510(k) Summary

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

Submitted by: Xiaoli Shi / David Zhang
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Date of Submission: 2010-4-30

Proposed Device: SeQure™ Snare System

Classification: Class II, MMX, 21 CFR 870.5150
Catheter, Percutaneous

Predicate Device: ev3 Amplatz "Goose Neck" Snare Device as cleared in K972511.

Intended Use: The SeQure™ Snare System is intended for use in the cardiovascular system as a tool to retrieve and manipulate foreign objects

Device Description: The SeQure™ Snare System consists of a snare, a catheter, a loader and a torquer. The snare is constructed of a nitinol shaft and a loop with the plane of the loop perpendicular to the nitinol shaft. The nitinol loop is covered with a tungsten coil which is coated by laminated titanium and its nitride to enhance radiopaque. The pre-formed snare loop can be introduced through catheter without risk of permanent deformation because of super-elasticity of nitinol material. The catheter consists of luer connector and PE tubing with a radiopaque markband at its distal tip to enhance the visibility during the operation. The snare is pre-assembled with the loader and the torque, and then packaged together with corresponding catheter.

Comparation with Predicate device:
The design, dimension, components, structure and fundamental technology of SeQure™ Snare System are all identical with predicate device ev3 Amplatz "Goose Neck" Snare,

Performance Data: Performance testing was conducted to validate and verify that the proposed device met all design specifications and was substantially equivalent to the predicate device:

- Dimension

- Delivery and Retrieving
- Torque Strength
- Tensile Strength
- Biocompatibility
- Package

SE Conclusion: The SeQure™ Snare System is safe and effective as Predicate Device ev3 Amplatz "Goose Neck" Snare Device based on performance testing.

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 Herbert Barkhuysen
KEMA Quality B.V.
Business Line Medical
P.O. Box 5185, 6802 ED Arnhem
The Netherlands

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Re: K102484
Trade/Device Name: SeQure Snare System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (Two)
Product Code: MMX
Dated: October 29, 2010
Received: November 2, 2010

Dear Mr. Barkhuysen:

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

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SeqCare™ Lifetech Scientific

Section II Indication for Use Statement

510(k) Number: K102484

Device Name: SeQure™ Snare System

Indications for Use:

The SeQure™ Snare System is intended for use in the cardiovascular system as a tool to retrieve and manipulate foreign objects.

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. Vo

(Division Sign-Off)
Division of Cardiovascular Devices

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