K061171
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510(k) Summary
for the BioSphere Medical, Inc.
Sequitor™ Steerable Guidewire

1. SUBMITTER/510(K) HOLDER

JUN - 2 2006

BioSphere Medical, Inc.
1050 Hingham Street
Rockland, MA 02370 USA

Contact Person: Irina Kulinets, Senior Director Regulatory Affairs and Quality Assurance
Telephone: 781-681-7900

Date Prepared: April 12, 2006

2. DEVICE NAME

Proprietary Name: Sequitor™ Steerable Guidewire
Common/Usual Name: Vascular Guidewire
Classification Name: Catheter Guidewire

3. PREDICATE DEVICES

- Radius Medical Cougar Guidewire (K011287 AND K032129)
- Boston Scientific Corporation, Transend Guidewire (K022357)

4. DEVICE DESCRIPTION

The Sequitor™ Steerable Guidewire (.014" or .018") is a stainless steel guidewire with a polymer distal tip and a radiopaque distal tip that is shapeable. The distal 50 cm is coated with a hydrophilic coating. The guidewire length is depicted on the product label.

5. INTENDED USE

The Sequitor™ Steerable Guidewire is intended to facilitate the placement of catheters within the peripheral vasculature for various diagnostic and interventional procedures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

BioSphere Medical, Inc. bases its claim of the substantial equivalence of the Sequitor™ Steerable Guidewire with the cited predicate devices based on intended use, indications for use, fundamental technological characteristics, and fundamental operational characteristics. In all cases, the guidewires are used to navigate to target areas of the vascular anatomy and provide support to additional tools, such as microcatheters. Accurate placement is assured through visualization of the radiopaque portions of the guidewire using fluoroscopic imaging. Like predicate devices, the Sequitor™ Steerable Guidewire is available in a range of sizes to permit selection of the most appropriate size for the vasculature and the therapeutic and diagnostic tools. All cited guidewires are intended for singe use and are provided sterile.

7. PERFORMANCE TESTING

In-vitro and in-vivo design verification and validation testing demonstrates that the Sequitor™ Steerable Guidewire fulfills design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2006

BioSphere Medical, Inc.
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K061171
Sequitor™ Steerable Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 24, 2006
Received: May 25, 2006

Dear Ms. Robinson:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachman

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

Enclosure

510(k) Number (if known): K061171

Device Name: BioSphere Sequitor™ Steerable Guidewire

Indications for Use:

The Sequitor™ Steerable Guidewire is intended to facilitate the placement of catheters within the peripheral vasculature for various diagnostic and interventional procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061171