## 6. 510(k) Summary

JAN 2 4 2013

### Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875

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E. Contact Person: Meghal Khakhar

F. Summary Prepared on: September 18, 2012

### Device Identification

A. Device Trade Name: SureFlex™ Steerable Guiding Sheath Kit

B. Device Common Name: Catheter Introducer

C. Classification Name: 21 CFR 870.1340

D. Product Code: DYB

E. Device Class: Class II

### Identification of Predicate Devices

| Predicate Device | Manufacturer | 510(k) No. |
|---|---|---|
| Agilis NxT Steerable Introducer | St. Jude Medical | K061363 |
| | | K081645 |

### Indications for Use

The SureFlex™ Steerable Guiding Sheath Kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

**Device Description**

The SureFlex™ Steerable Guiding Sheath Kit is a single-use device which is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The kit contains a steerable sheath, a dilator, and a guidewire. The steerable sheath is comprised of a stainless steel braided nylon tube with a soft, pebax distal tip. A platinum/iridium marker band is positioned near the distal tip to ensure precise tracking and placement of the sheath during procedures. The sheath is finished at the proximal end with a hemostasis valve and 2.distal side ports with a 3-way stopcock for the injection or aspiration of fluids. The steerable sheath comes in small, medium, and large curve options which can be deflected 90° counter-clockwise and 180° clockwise. The dilator is comprised of an HDPE tube with a tapered tip and has a male luer hub connector at the proximal end for connection to the sheath. The guidewire is stainless steel and coated with PTFE.

**Substantial Equivalence**

The SureFlex™ Steerable Guiding Sheath Kit is determined to be substantially equivalent to the predicate devices with respect to intended use, design, technological characteristics, and principles of operation. This determination is based on the results of performance tests as listed below:

i) Biocompatibility Testing

The SureFlex™ Steerable Guiding Sheath Kit meets the requirements of the following biocompatibility requirements:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaenous Reactivity
- Systemic Toxcitiy (Acute)
- Hemocompatibility (including Hemolysis and Thrombosis)

ii) Mechanical Testing

The SureFlex™ Steerable Guiding Sheath Kit can withstand the following mechanical stresses without failure:

- Torque Transmission and Strength of Union Torque Test
- Freedom from Liquid Leakage through Hemostasis Valves
- Freedom from Air Leakage through Hemostasis Valve
- Freedom from Liquid Leakage
- Freedom from Air Leakage
- Strength of Union Pull Test
- Tip Transition
- Snap Fit
- Valve Insertion Force

iii) Physical Testing

The SureFlex™ Steerable Guiding Sheath Kit has passed the following physical tests:

- Surface Defects
- Range of Motion + Geometry
- Curve Retention + Integrity Test
- Corrosion Resistance
- Friction Testing
- Handle Lubricity
- Tip Stiffness

v) Bench Testing

Bench testing was conducted to determine that the SureFlex™ Steerable Guiding Sheath Kit is compatible for use with 8.5F devices in a clinical setting.

vi) Radiopacity and Particulate Testing

The following validation tests were performed on the SureFlex™ Steerable Guiding Sheath Kit:

- Radiopacity
- Particulate

The SureFlex™ Steerable Guiding Sheath Kit is determined to be substantially equivalent to the predicate devices based on the performance tests described above. The technological differences between the proposed and predicate devices do not raise any new concerns of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

JAN 2 4 2013

Baylis Medical Co., Inc
Meghal Khakhar
2645 Matheson Blvd. E
Mississauga, Ontario
CA L4W 5S4

Re: K122926
Trade/Device Name: Sureflex Steerable Guiding Sheath Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 19, 2012
Received: December 21, 2012

Dear Meghal Khakhar:

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,

Matthew G. Hillebrenner

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

Enclosure

## Indications for Use

510(k) Number (if known): K122926

Device Name: SureFlex™ Steerable Guiding Sheath Kit

Indications for Use:

The SureFlex™ Steerable Guiding Sheath Kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122926