



Food and Drug Administration  
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December 4, 2015

Synaptic Medical Ltd  
c/o Diana Hong  
Mid-Link Consulting Co., Ltd  
P.O. Box 120-119  
Shanghai, CN 200120

Re: K151936

Trade/Device Name: Steerable Intracardiac Catheter Introducer Kit and Transseptal Needle  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: October 23, 2015  
Received: November 3, 2015

Dear Diana 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Kenneth J. Cavanaugh -S**

for

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)

Device Name

Steerable Intracardiac Catheter Introducer Kit and Transseptal Needle

Indications for Use (Describe)

The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **Exhibit # 3 510(k) Summary**

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

The assigned 510(k) Number: K151936

1. Date of Preparation: 10/20/2015
2. Sponsor

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3. Submission Correspondent

Ms. Diana Hong (Primary Contact Person)  
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#### 4. Identification of Proposed Device

Trade Name: Steerable Intracardiac Catheter Introducer Kit and Transseptal Needle

Common Name: Catheter Introducer

Regulatory Information:

Classification Name: Introducer, Catheter

Classification: II;

Product Code: DYB;

Regulation Number: 21 CFR 870.1340;

Review Panel: Cardiovascular;

Intended Use Statement:

The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

#### Device Description

The proposed device includes Steerable Intracardiac Catheter Introducer Kit as well as its accessory, Transseptal Needle. The Steerable Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart, including both right and left side. When left side of heart is accessed, Transseptal Needle is intended for puncture the interatrial septum during a transseptal catheterization procedure.

The Steerable Intracardiac Catheter Introducer Kit includes three components, which are (1) steerable sheath introducer, (2) dilator and (3) guidewire. The steerable sheath introducer is introduced into a body vessel, along with the dilator, over the guidewire, it is available in variable specification and curve configuration; Dilator is assembled with the sheath introducer and introduced into a body vessel over the guidewire. It is used to provide support to sheath and ensure smooth advancement; the guidewire is percutaneous placed into the body vessel to function as a guide for the introduction into the chambers of the heart.

The handle of Steerable Intracardiac Catheter Introducer is equipped with the rotation collar, turn the collar in clockwise, the tip can be steered from 0 to 180 degree(s), while turn the collar in counterclockwise, the tip can be steered from 0 to 90 degree(s) on the other side.

The transseptal needle includes two components, which are (1) needle and (2) stylet. The needle is used to puncture the interatrial septum during a transseptal catheterization procedure; the stylet is used to keep the needle lumen intact during handling and facilitate the needle advancement within the dilator.

The kit and the transseptal needle are provided sterilized. They are subject to Ethylene Oxide sterilization prior to release. The Sterility Assurance Level (SAL) is  $10^{-6}$ .

The shelf life of the proposed device is three (3) years.

#### 5. Identification of Predicate Device

510(k) Number: K081645

Product Name: Agilis™ NxT Steerable Introducer

Manufacturer: St. Jude Medical

#### 6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 11070-2014 Sterile single-use intravascular catheter introducer;
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F 756-08, Standard practice for assessment of hemolytic properties of material;
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1140-07 (Reapproved 2012), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.

#### 7. Clinical Test Conclusion

No clinical study is included in this submission.

## 8. Substantially Equivalent (SE) Comparison

Table 6-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Devices K081645
Product Code	DYB	DYB
Regulation Number	21 CFR 870.1340	21 CFR 870.1340
Intended Use	The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	The Agilis™ NxT Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.
Sterile	EO Sterilized	EO Sterilized
Single Use	Yes	Yes
Shelf Life	3 years	3 years
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1
Performance	Comply with ISO 11070-1998	Comply with ISO 11070-1998
Feature	Steerable sheath introducer tip	Steerable sheath introducer tip
	Curl at sheath introducer tip	Curl at sheath introducer tip
	Radiopaque	Radiopaque
	Curve at needle Transseptal Needle tip	Curve at needle Transseptal Needle tip
	J Shape Guidewire	J Shape Guidewire

## 9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.