DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 29, 2014

Synaptic Medical Limited
% Diana Hong
General Manager
Mid-Link Consulting
P.O. Box 120-119
Shanghai, 200120 CH

Re: K132943
Trade/Device Name: Intracardiac Catheter Introducer Kit and Transseptal Needle
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, NKQ, DRC
Dated: July 24, 2014
Received: July 28, 2014

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. 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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

Enclosure

**Tab # 6 Indications for Use Statement**

510(k) Number: K132943

Device Name: Intracardiac Catheter Introducer Kit and Transseptal Needle

Indications for Use:

Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart. Transseptal Needle is intended for puncture the interatrial septum during a transseptal catheterization procedure.

| ☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) | OR | ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C) |
|---|---|---|

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Tab # 7 510(k) Summary**

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

The assigned 510(k) Number: K132943

7.1 Date of Preparation

8/29/2014

7.2 Sponsor

**Synaptic Medical Limited**

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7.3 Submission Correspondent

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7.4 Identification of Proposed Device

Trade Name: Intracardiac Catheter Introducer Kit and Transseptal Needle
Common Name: Catheter Introducer and Trocar

Regulatory Information:
Classification Name: Introducer, Catheter
Classification: II;
Product Code: DYB;
Regulation Number: 21 CFR 870.1340;
Review Panel: Cardiovascular;

Regulatory Information:
Classification Name: Trocar
Classification: II;
Product Code: DRC;
Regulation Number: 21 CFR 870.1390;
Review Panel: Cardiovascular;

Regulatory Information:
Classification Name: Guidewire, Catheter, Reprocessed
Classification: II;
Product Code: NKQ;
Regulation Number: 21 CFR 870.1330;
Review Panel: Cardiovascular;

Intended Use Statement:

Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart. Transseptal Needle is intended for puncture the interatrial septum during a transseptal catheterization procedure.

7.5 Device Description

The proposed device includes Intracardiac Catheter Introducer Kit as well as its accessory, Transseptal Needle. Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart, including both right side 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 Intracardiac Catheter Introducer Kit includes three components, which are (1) sheath introducer, (2) dilator and (3) guidewire. The 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 transseptal needle includes two components, which are (1) needle and (2) stylet. The needle is used to puncture the the interatrial septum during a transseptal catheterization procedure; the stylet is used to keep the needle luman intact during handling and facilitate the needle advancement within the dilator.

7.6 Identification of Predicate Device

510(k) Number: K070417
Product Name: ACross™ Transseptal Access System
Manufacturer: St. Jude Medical

7.7 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 11070-1998 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;
- 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.

In addition to the following standards, the following test items have also been performed to evaluate the proposed device:

- Simulated Use Testing
- Anti-kink Testing;
- Torque Strength Testing;
- Torqueability Testing;
- Tip Flexibility Testing;
- Flow Rate Testing;
- Coating Integrity;
- Particulate Evaluation.

7.8 Clinical Test Conclusion

No clinical study is included in this submission.

7.9 Substantially Equivalent (SE) Comparison

Table 6-1 Comparison of Technology Characteristics

| Item | Proposed Device(s) | Predicate Device(s) |
|---|---|---|
| Product Code | DYB | DYB |
| Regulation Number | 21 CFR 870.1340 | 21 CFR 870.1340 |
| Intended Use | Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart. Transseptal Needle is intended for puncture the interatrial septum during a transseptal catheterization procedure. | The St. Jude Medical ACross™ Transseptal Access System is used both to puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart. |
| 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 |
| Features | Curve at sheath introducer tip | Curve at sheath introducer tip |
| | Radiopaque | Radiopaque |
| | Curve at needle Transseptal Needle tip | Curve at needle Transseptal Needle tip |
| | J Shape Guidewire | J Shape Guidewire |

7.10 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.