DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 19, 2017

AngioDynamics, Inc.
Hans Kjolhede
Specialist 1, Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K170775
Trade/Device Name: Mini Stick ENVI Non-Vascular Introducer Kit
Regulation Number: 21 CFR§ 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB, GBX, GAA
Dated: June 16, 2017
Received: June 19, 2017

Dear Hans Kjolhede:

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 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" (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 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170775

Device Name

Mini Stick ENVI Non-Vascular Introducer Kit

Indications for Use *(Describe)*

The Mini Stick ENVI Non-Vascular Introducer Kit is utilized to facilitate the introduction and placement of a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) diameter guidewire for non-vascular procedures.

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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510(k) Summary for the Mini Stick ENVI Non-Vascular Introducer Kit

Date prepared: July 19, 2017

A. Sponsor

AngioDynamics, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Hans Kjolhede	Wanda Carpinella
Global Regulatory Affairs	Director, Regulatory Affairs
(508) 658-7944	(508) 658-7990

C. Device Name

Trade Name:	Mini Stick ENVI Non-Vascular Introducer Kit
Common/Usual Name:	Non-Vascular Introducer Kit
Classification:	Class II, 21 CFR §870.1340-ProCode: DYB Class I, 21 CFR §878.4200-ProCode: GBX Class I, 21 CFR §878.4800-ProCode: GAA
Classification Name:	Biliary Catheter and Accessories (Gastroenterology and Urology Panel) Introduction/Drainage Catheter and Accessories (General and Plastic Surgery Panel) Needle, Aspiration and Injection, Disposable (General and Plastic Surgery Panel)

D. Predicate Device(s)

Manufacturer:	Boston Scientific Corporation
Predicate Name:	AccuStick Introducer System
Predicate 510(k):	K952828
Classification:	Class II, 21 CFR §870.1340-ProCode: DYB Class I, 21 CFR §878.4200-ProCode: GBX
Classification Name:	Catheter Introducer Introduction/Drainage Catheter and Accessories

E. Reference Devices

Cook Neff Percutaneous Access Set	K895044
Cook Percutaneous Trocar Needle	Exempt per 878.4800
Cook Skinny Needle with Chiba Tip	K851957 (Now exempt per 878.4800)

F. Device Description

The Mini Stick ENVI Non-Vascular Introducer Kit contains one or more of the following components. Reference unit label for specific devices: Triaxial Sheath/Dilator assembly with stiffening cannula; 18G (1.4 mm) or 21G (0.9 mm) needle with stylet; 0.018 in (0.46 mm) floppy tip guidewire; 0.035 in (0.89 mm) or 0.038 in (0.97 mm) heavy duty guidewire. For user convenience, all kit components are also available in multiple kit configurations as sterile, standalone devices.

G. Intended Use/Indications for Use

The Mini Stick ENVI Non-Vascular Introducer Kit configurations are indicated as follows:

- The Mini Stick ENVI Non-Vascular Introducer Kit is utilized to facilitate the introduction and placement of a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) diameter guidewire for non-vascular procedures.

H. Technological Characteristics

The proposed device has similar materials, design and components and technological characteristics as predicate and referenced devices.

Predicate Comparison Table		
	Proposed Mini Stick ENVI Kit	Boston Scientific AccuStick Introducer System **(K952828)**
Indications for Use	The Mini Stick ENVI Non-Vascular Introducer Kit is utilized to facilitate the introduction and placement of a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) diameter guidewire for non-vascular procedures.	The AccuStick™ II Introducer System with radiopaque marker facilitates introduction and placement of a guidewire.
Intended Use	Placement of guidewire in non-vascular procedures.	Placement of guidewire in non-vascular procedures.
Sheath Introducer OD/Dilator ID	6F/4F	6F/4F
Triaxial Sheath Length	20cm	20cm
Stiffening Cannula Option	Yes	Yes
Sheath Radiopaque Marker	Yes	Yes
RO Marker	Radiopaque Marker Tip	Radiopaque Marker Tip
Introducer Needle Sizes*	18G & 21G	21G
Guidewire Sizes	0.018 in. 0.035 in. 0.038 in.	0.018 in. 0.038 in.

*The reference devices are being cited to support substantial equivalence pertaining to needle configurations.

I. Performance Data

The proposed Mini Stick ENVI Non-Vascular Introducer Kit is substantially equivalent to the specified predicate device based on a comparison of technological characteristics and the results of non-clinical test performed in accordance with ISO 11070: *Sterile, Single-Use Intravascular, Introducers, Dilators and Guidewires*: 2014 and ISO 594-2: *Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Medical Equipment - Part 2* (1998), which included:

- Tensile Testing
- Leak Testing
- Radiopacity Testing
- Dimensional verification
- Compatibility Testing

- Luer performance
- Corrosion Resistance
- Biocompatibility per ISO 10993-1

J. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent