



Food and Drug Administration
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October 1, 2015

Sonostik, LLC
Richard Fogel
CEO
14410 Turkey Foot Road
North Potomac, Maryland 20878

Re: K152177
Trade/Device Name: Sonostik Guide Wire Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 31, 2015
Received: August 4, 2015

Dear Mr. Fogel:

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 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)

K152177

Device Name

SonoStik Guide Wire Introducer

Indications for Use (Describe)

The SonoStik Guide Wire Introducer is used to facilitate the introduction of a guide wire and catheter through the skin into a vein or artery of the peripheral vasculature. The SonoStik Guide Wire Introducer is not intended for use in the coronary arteries or neurovasculature.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K152177

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the SonoStik Guide Wire Introducer is provided below.

Device Common Name:	Catheter Introducer
Device Proprietary Name:	SonoStik Guide Wire Introducer
Submitter:	SonoStik, LLC 14410 Turkey Foot Road N. Potomac, MD 20878
Correspondent:	Richard Fogel CEO, SonoStik, LLC 14410 Turkey Foot Road N. Potomac, MD 20878 301-219-8552 dickfogel@gmail.com
Classification Regulation:	21 CFR 870.1340, Catheter Introducer, Class II
Panel:	Cardiovascular
Product Code:	DYB – Catheter Introducer
Date Prepared:	09/15/15
Primary Predicate Device:	Pinnacle Precision Access System, Terumo Medical Corp. (K111606)
Additional Predicate Device:	Endologix Guidewire, TechDevice Corporation (K110241)

Indication for Use:

The SonoStik Guide Wire Introducer is used to facilitate the introduction of a guide wire and catheter through the skin into a vein or artery of the peripheral vasculature. The SonoStik Guide Wire Introducer is not intended for use in the coronary arteries or neurovasculature.

Device Description:

The SonoStik Guide Wire Introducer is intended to facilitate placing a catheter through the skin into a vein or artery of the peripheral vasculature. The device consists of a plastic housing containing an Introducer Wheel, an Advancing Wheel and a guide wire. The mechanism of action of the SonoStik Guide Wire Introducer is accomplished by the Introducer Wheel and the two Advancing Wheels inside the plastic housing. The SonoStik Guide Wire Introducer housing has a “male end” connector capable of mating with the back end of the needle introducer and accurately positions the guide wire through the plastic housing and into the back end of the needle. Once mated, the Introducer and cannula/needle are used to insert the needle into the tissue or vessel. The Introducer Wheel is turned, advancing the guide wire into the vessel lumen. The device has a transparent tube at the proximal end of the device which enables the user to visualize guide wire advancement as he/she engages the introducer wheel.

The SonoStik Guide Wire Introducer is intended to be used with one of two IV catheter and needle sets that have been previously cleared under 510(k) Premarket Notification. The two compatible IV catheter and needle sets are the B Braun Introcan Safety IV Catheter (K020785) and BD Angiocath IV (K950301).

Biocompatibility

In accordance with ISO 10993, the contact category of SonoStik Guide Wire Introducer is: Externally Communicating Devices, Circulating Blood, Limited Exposure (>24 hrs). The following biocompatibility testing was conducted on the patient contacting and potentially blood contacting materials:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Irritation / Intracutaneous Reactivity ISO 10993-10
- Systemic Toxicity ISO 10993-11
- Pyrogenicity ISO 10993-11
- Thrombogenicity ISO 10993-4
- Hemocompatibility ISO 10993-4

Sterilization

The SonoStik Guide Wire Introducer is provided sterile. It is for single use only. The device is not sold with any additional accessories or components. The device is sterilized using traditional Ethylene Oxide and was validated in accordance with ANSI/AAMI/ISO 11135-1: 2007.

Shelf Life

The shelf life for the SonoStik Guide Wire Introducer is 1 year. Shelf life testing was conducted to demonstrate that the device maintains sterility and functionality throughout its shelf life.

Performance Data

The following tests were conducted on the SonoStik Guide Wire Introducer to validate the design, manufacture, assembly, and performance:

1. Visual Inspection. This test demonstrated that the device as manufactured meets dimensional specifications and is free of surface defects.
2. Cycling Test. This test demonstrated that all moving components of the device can withstand repeated and repetitive use without failure or deterioration of function, with and without mated catheter needle set.
3. Simulated Use Test. This test demonstrated that the device can perform the required steps in administering a venous catheter using a rubber arm phantom with simulated blood under average venous blood pressure.
4. Guide Wire Tensile Test. This test demonstrated that that the guide wire will not fragment or separate during normal operation, as well as quantifying the amount of guide wire travel.

5. Corrosion Test. This test demonstrated that the guide wire exhibits corrosion resistance comparable to fully assembled devices over a 1-year shelf-life when tested in accordance with ISO 11070:2014(E).

All devices tested passed all tests. Therefore, data and results from the above tests demonstrate that the SonoStik Guide Wire Introducer meets its performance requirements, and can be found substantially equivalent to the performance of the predicate devices.

Substantial Equivalence Discussion

The primary predicate device for the SonoStik Guide Wire Introducer is the Pinnacle Precision Access System (K111606). The guide wire used in the subject device was previously cleared in K110241 and is therefore provided as an additional predicate device to support substantial equivalence. Like the predicate devices, the subject device is indicated for use to facilitate the introduction of a guide wire and catheter through the skin into a vein or artery. Therefore the indication statement of the subject device is substantially equivalent to the predicate devices.

The SonoStik Guide Wire Introducer and the Pinnacle Precision Access System (K111606) have similar components which function in the same manner and similar device specifications. Material differences and specification differences between the devices do not raise different questions of safety and effectiveness. A detailed comparison of the technological characteristics is provided in the following table.

	Proposed Device	Primary Predicate Device
Device Name	SonoStik Guide Wire Introducer	Pinnacle Precision Access System
510(k) Number	K152177	K111606
Submitter	SonoStik, LLC	Terumo Medical Corp.
Classification Regulation	Catheter Introducer 870.1340	Catheter Introducer 870.1340
Product Code	DYB	DYB
Panel	Cardiovascular	Cardiovascular
Guide Wire Material	Stainless steel	Stainless steel or Nitinol w/Palladium distal coil
Guide Wire Length	19.5cm	45cm
Guide Wire OD	.014"	.021"
Guide Wire Inserter	Polycarbonate	Polypropylene
Plastic Housing	Polycarbonate	NA

Substantial Equivalence Conclusion:

On the basis of the above comparison of intended use and technological characteristics, the differences between the SonoStik Guide Wire Introducer and the Pinnacle Precision Access System do not raise different questions of safety and effectiveness and the devices can be found substantially equivalent.