November 4, 2024

SonoStik, LLC
% Robert Mclain
Sr. Quality and Regulatory Affairs Consultant
Keystone Regulatory Services, LLC
342 E. Main Street
Suite 207
Leola, Pennsylvania 17540

Re: K243061
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: September 27, 2024
Received: October 29, 2024

Dear Robert Mclain:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2024.11.04 10:35:26 -05'00'

Finn Donaldson
Assistant Director (Acting)
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243061

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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Contact Details

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Device Name

Device Trade Name

SonoStik Guide Wire Introducer

Common Name

Catheter introducer

Classification Name

Introducer, Catheter

Regulation Number

870.1340

Product Code

DYB

Legally Marketed Predicate Device

The proposed SonoStik Guide Wire Introducer is substantially equivalent to the SonoStik, LLC SonoStik Guide Wire Introducer (Product Code DYB) cleared under K152177.

Device Description Summary

The SonoStik Guide Wire Introducer is intended to facilitate the introduction of a guide wire and catheter through the skin into a vein or artery of the peripheral vasculature. The device consists of a plastic housing containing an Introducer Wheel, Advancing Wheels, 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 a compatible 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 they engage the introducer wheel.

The SonoStik Guide Wire Introducer is compatible with and intended to be used with the MedSource Labs VeroTrue Conventional IV Catheter (K193278 catheter and needle set in 18-, 20-, and 22-gauge sizes.

Intended Use/Indications 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.

Indications for Use Comparison

The proposed SonoStik Guide Wire Introducer shares identical indications for use with the predicate device (K152177 - SonoStik Guide Wire Introducer).

Technological Comparison

The proposed SonoStik Guide Wire Introducer shares the following identical technical characteristics with the predicate device (K152177 - SonoStik Guide Wire Introducer): classification regulation, product code, panel, indication for use, sterilization method, and materials of construction with the exception of the following.

The proposed product's guide wire is composed of nitinol, is 218 mm in length, and features a taper from a distal outer diameter of 0.09 mm to 0.24 mm after the first 47.5 mm of distal length whereas the predicate's (K152177 guide wire is stainless steel, is 195 mm in length, and has a uniform outer diameter of 0.36 mm inches. To accommodate the change in guide wire length, the polycarbonate device housing and sterile barrier packaging pouch seal were lengthened compared to the predicate. Additionally, a new brand of cannulated needle and catheter sets in 18-, 20-, and 22-gauge sizes was qualified as compatible with the proposed product. Design control testing demonstrated that these changes do not negatively impact the performance of the proposed device when compared to the predicate.

Non-Clinical Tests Summary and Conclusions

SonoStik LLC performed worst-case non-clinical testing in which the proposed SonoStik Guide Wire Introducer was assessed for biocompatibility, bacterial endotoxin, and packaging performance and product performance following worst-case sterilization, distribution simulation, environmental conditioning, and 1-year accelerated aging. Testing found the SonoStik Guide Wire Introducer met all applicable acceptance criteria associated with the introduction of a guide wire and catheter through the skin into a vein or artery of the peripheral vasculature. The testing supported the substantial equivalence of the subject device to the predicate device.