August 28, 2023

Soundbite Medical Solutions, Inc.
Diane Marceau
Director, Quality Assurance and Regulatory Affairs
2300 Alfred Nobel, Suite 230
Montreal, Quebec H4S 2A4
Canada

Re: K230159
Trade/Device Name: SoundBite® Crossing System XS Peripheral
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: July 18, 2023
Received: July 18, 2023

Dear Diane Marceau:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.08.28 11:45:39 -04'00'

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230159

Device Name
SoundBite® Crossing System XS Peripheral

Indications for Use *(Describe)*
The SoundBite® Crossing System XS Peripheral is indicated to facilitate the intraluminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions.

The SoundBite® Crossing System XS Peripheral is not intended for use in the carotid arteries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SoundBITE 510(k) Summary K230159

As required by 21 CFR 807.92

Date Prepared:	August 25, 2023
Trade/Device name:	SoundBite® Crossing System XS Peripheral
Common Name:	System for Crossing Total Occlusions
Classification Name:	Catheter for Crossing Total Occlusions
Classification Product Code:	PDU
Regulation:	21 CFR 870.1250, Percutaneous Catheter
Regulatory Class:	Class II
Manufacturer:	Soundbite Medical Solutions, Inc. 2300 Alfred Nobel, Suite 230 Montreal, QC H4S 2A4, Canada
Establishment Registration No.:	3013290687
Regulatory Contact:	Diane Marceau Director, Quality Assurance and Regulatory Affairs Tel: (514) 956-2525 x 3352 Email: diane.marceau@soundbitemedical.com
Predicate Device:	SoundBite® Crossing System – Peripheral (14P) [K210839]
Reference Device:	SoundBite® Crossing System – Peripheral [K192211]

Device Description:

The SoundBite® Crossing System XS Peripheral, is a recanalization device designed to help physicians place a conventional guidewire or treatment device in the intraluminal space beyond peripheral chronic total occlusions (CTOs). It is intended for use in a professional healthcare facility, such as a catheterization laboratory, also known as a Cath Lab. The system consists of the AC-powered, reusable, mobile SoundBite® Console XS with a Foot Switch, and a single-use, sterile SoundBite® Active Wire XS 14P packaged together with two accessories, the SoundBite® Curving Tool 14 and the SoundBite® Torquer.

The AC-powered, reusable, mobile SoundBite® Console XS is an iteration of the predicate device, re-engineered for improved usability but with similar design, functional, safety, and performance specifications. It generates controlled, high-amplitude, short-duration mechanical pulses (i.e., shock waves) that are transmitted to the connected SoundBite® Active Wire XS 14P and cause the distal end of the wire to move back and forth (axially), acting like a micro-jackhammer.

The single-use SoundBite® Active Wire XS 14P is a 350 cm long metallic wire with an outer diameter of 0.36 mm (0.014") over its usable length. It is similar in construction to the Active Wire of the predicate and reference devices, but 50 cm longer. The proximal end of the SoundBite® Active Wire XS 14P includes a connector assembly that encapsulates a wire section reducer for easy connection to the SoundBite® Console XS, and a Radio Frequency Identification (RFID) tag that allows the SoundBite® Console XS to detect and uniquely identify the wire and track its use. A thermoplastic elastomer sleeve was also added to protect the proximal length of the wire during use.

Intended Use / Indications for Use:

The SoundBite® Crossing System XS Peripheral is indicated to facilitate the intraluminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions.

The SoundBite® Crossing System XS Peripheral is not intended for use in the carotid arteries.

Substantial Equivalence Comparison:

The SoundBite® Crossing System XS Peripheral has the same intended use and indications for use, the same fundamental technology and principles of operation, and substantially equivalent technological characteristics as the predicate device, the SoundBite® Crossing System – Peripheral (14P) (K210839). A side-by-side comparison of key device characteristics is presented in the following table:

Device Characteristic	SoundBite® Crossing System – Peripheral (14P) / K210839	SoundBite® Crossing System XS Peripheral
Mechanism of Action	Mechanical pulses sent along the length of the SoundBite® Active Wire cause the distal tip to accelerate axially in a reciprocating (back-and-forth) motion, acting like a micro-jackhammer.	Mechanical pulses sent along the length of the SoundBite® Active Wire cause the distal tip to accelerate axially in a reciprocating (back-and-forth) motion, acting like a micro-jackhammer.
Mobile Console	SoundBite® Console	SoundBite® Console XS
Energy Source	AC mains-powered	AC mains-powered
Software System	Firmware only	Firmware and Linux-based Software
User Interface	20-character monochrome screen, 4 physical knobs, 4 lights	10-inch color, touchscreen on the operator side; 3-inch color, LCD on the physician side
Wire Identification	No	Radiofrequency identification (RFID)
Wire Tracking	No	Defect logging and usage time tracking
Wire Monitoring	No	Connection quality and tip activity monitoring
Wire Activation Means	Foot Switch	Foot Switch
Dimensions	130 cm x 59 cm x 49 cm	106 cm x 55 cm x 30 cm
Weight	160 kg	64 kg
Sound Level when Active	70 dB	< 55 dB
Electrical Safety and EMC	ANSI/AAMI ES60601-1:2005+A1:2012 IEC 60601-1-2:2014 (Ed. 4)	ANSI/AAMI ES60601-1:2005+A1:2012 IEC 60601-1-2:2014 (Ed. 4) FCC Part 15 Subpart B
Active Wire	SoundBite® Active Wire 14P	SoundBite® Active Wire XS 14P
Wire Identification	No	Radiofrequency identification (RFID)
Wire Connection to the SoundBite® Console	Titanium alloy section reducer (requires manual alignment and locking)	Titanium alloy section reducer with self-aligning, self-locking connector
Proximal Wire Sleeve	No (Off-the-shelf sterile sheath specified)	Thermoplastic elastomer sleeve (100 cm)
Wire Length	300 cm	350 cm
Wire Working Length	145 cm	175 cm
Radiopaque Marker	10 mm radiopaque coil starting at 0.75 mm from the distal tip	10 mm radiopaque coil starting at 0.75 mm from the distal tip
Wire Diameter	0.36 mm (0.014”)	0.36 mm (0.014”)
Wire Tip Diameter	0.27 mm (0.0105”)	0.28 mm (0.0109’’)
Wire Material	Titanium alloy	Titanium alloy
Wire Coating	PTFE (polytetrafluoroethylene) coating on main body of the wire; no coating on distal end	PTFE (polytetrafluoroethylene) coating on main body of the wire; no coating on distal end
Single-use	Yes	Yes
Wire Sold Sterile	Yes; Ethylene Oxide Sterilization	Yes; Ethylene Oxide Sterilization
Shelf Life	24 months	24 months
Sterile Accessories	SoundBite® Curving Tool Off-the-shelf Torquer	SoundBite® Curving Tool 14 SoundBite® Torquer

Summary of Non-Clinical Testing:

Design verification and validation testing was conducted in compliance with applicable FDA-recognized consensus standards, FDA guidance, and current industry standards following systematic risk assessment in accordance with ISO 14971:2019.

The SoundBite® Console XS was assessed for substantial equivalence with the SoundBite® Active Wire XS 14P (i.e., electrical and mechanical safety, electromagnetic compatibility, functionality, and serviceability).

The medical device software system has been designed, developed, and verified in compliance with IEC 62304.

Usability was assessed under anticipated use conditions in compliance with IEC 62366-1 and FDA guidance.

The sterility of the SoundBite® Active Wire XS 14P and its accessories to the point of care is assured by validated Ethylene Oxide sterilization processes, shelf-life testing, and sterile packaging integrity testing under foreseeable storage and transport conditions.

The biocompatibility of the SoundBite® Active Wire XS 14P was assessed in compliance with FDA-recognized standard ISO 10993-1 and FDA guidance for Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogenicity, and Hemocompatibility.

The safety and performance of the SoundBite® Active Wire XS 14P were assessed, where appropriate using the supplied accessories, in the following areas:

- Physical and dimensional specifications
- Console connection and disconnection force
- Proximal sleeve function
- Simulated use (crossing and durability)
- Wire coating integrity
- Particulates
- Corrosion resistance
- Lubricity in tortuous model
- Steerability
- Kink resistance
- Tensile strength on coil, proximal end assembly, and section reducer
- Torque strength
- Torqueability
- Tip flexibility
- Tip motion (maximum displacement)
- Tip motion (vessel damage)
- Tip temperature

Conclusion:

The results from risk assessment and non-clinical testing of the SoundBite® Crossing System XS Peripheral do not raise new questions of safety or effectiveness. The data submitted with this 510(k) premarket notification demonstrate that the SoundBite® Crossing System XS Peripheral is substantially equivalent to the predicate device.