April 20, 2021

Soundbite Medical Solutions, Inc.
Dominique Abecassis
Director, Compliance
2300 Boulevard Alfred-Nobel
Montreal, Quebec H4S 2A4
Canada

Re: K210839
Trade/Device Name: SoundBite Crossing System - Peripheral (14P)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PDU
Dated: March 18, 2021
Received: March 22, 2021

Dear Dominique Abecassis:

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,

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)*
K210839

Device Name
SoundBite® Crossing System - Peripheral (14P)

Indications for Use *(Describe)*
SoundBite® Crossing System - Peripheral (14P) is indicated to facilitate the intraluminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions.

SoundBite® Crossing System - Peripheral (14P) 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.

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510(K) Summary

As required by 21 CFR 807.92

Date Prepared:	15 March 2021
Submitted by:	Soundbite Medical Solutions, Inc. 2300 Boulevard Alfred-Nobel, Montreal, Quebec, Canada H4S 2A4
Contact:	Dominique Abecassis Director, Compliance Tel: (514) 956-2525 x 3352 Fax: (514) 956-2529 E-mail: dominique.abecassis@soundbitemedical.com
Trade/Device Name:	SoundBite® Crossing System – Peripheral (14P)
Common Name:	System for Crossing Total Occlusions
Regulation:	21 CFR 870.1250, Percutaneous Catheter
Device Class:	Class II
Product Code:	PDU (Catheter for Crossing Total Occlusions)
Predicate Device:	SoundBite® Crossing System – Peripheral by Soundbite Medical Solutions Inc. (K192211)

Device Description:

The SoundBite® Crossing System – Peripheral (14P) is a recanalization tool, designed to help physician's placement of conventional guidewires or treatment devices in the intraluminal space beyond chronic total occlusions in the peripheral vasculature. The SoundBite® Crossing System – Peripheral (14P) consists of the reusable mobile SoundBite® Console, a single-use sterile SoundBite® Active Wire 14P, and their respective accessories.

The SoundBite® Console generates controlled mechanical pulses (i.e., shock waves) which are transmitted to the SoundBite® Active Wire 14P and cause the distal tip of the wire to accelerate axially in a reciprocating motion, acting like a micro-jackhammer.

The SoundBite® Active Wire 14P is similar in construction to the 0.018" CTO crossing wire provided with the predicate device, with a friction reducing PTFE coating (except for the distal tip), a radiopaque marker near the tip, and enhanced flexibility at the distal end. It has an outer

diameter of 0.36 mm (0.014") and it is 300 cm long, with a working length of 145 cm. At the proximal end of the SoundBite® Active Wire 14P, a section reducer allows the wire to be connected to the SoundBite® Console. The single-use SoundBite® Active Wire 14P is supplied sterile with a shelf life of 24 months.

Intended Use / Indications for Use:

The SoundBite® Crossing System – Peripheral (14P) is indicated to facilitate the intraluminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions.

The SoundBite® Crossing System – Peripheral (14P) is not intended for use in the carotid arteries.

Substantial Equivalence Comparison:

The SoundBite® Crossing System – Peripheral (14P) is substantially equivalent to the predicate device, the SoundBite® Crossing System – Peripheral (K192211), in intended use and indications for use, fundamental technologies, principles of operation, and labeling. Non-clinical bench testing data, and performance data from animal studies have been submitted to demonstrate that the differences in device characteristics do not raise questions related to safety or performance. A side-by-side comparison of key device characteristics is presented in the following table:

Device Characteristic	**Predicate Device 510(k) K192211 SoundBite® Crossing System – Peripheral**	**SoundBite® Crossing System – Peripheral (14P)**
System Components	▪ AC-powered, mobile SoundBite® Console generator and footswitch. ▪ Single-use SoundBite® Active Wire 18	▪ AC-powered, mobile SoundBite® Console generator and footswitch. ▪ Single-use SoundBite® Active Wire 14P
Mechanism of Action	Mechanical pulses sent along the length of the Titanium alloy 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 Titanium alloy SoundBite® Active Wire cause the distal tip to accelerate axially in a reciprocating (back-and-forth) motion, acting like a micro-jackhammer.
Console Setting: Pulse Repetition Rate (PRR)	10 Hz	20 Hz
Wire Connection	Titanium alloy section reducer for connection to the SoundBite® Console	Titanium alloy section reducer for connection to the SoundBite® Console
Maximum Active Wire Diameter over Usable Length	0.46 mm (0.018")	0.36 mm (0.014")
Working Length	150 cm	145 cm
Radiopaque Marker	10 mm radiopaque coil starting at 1.5 mm from the distal tip	10 mm radiopaque coil starting at 0.75 mm from the distal tip

Device Characteristic	Predicate Device 510(k) K192211 SoundBite® Crossing System – Peripheral	SoundBite® Crossing System – Peripheral (14P)
Wire Shaft Diameter	0.46 mm (0.018")	0.36 mm (0.014")
Wire Tip Diameter	0.29 mm (0.0115")	0.27 mm (0.0105")
Wire Material	Titanium alloy	Titanium alloy
Wire Coating	PTFE coating on main body of the wire only; no coating on distal end	PTFE coating on main body of the wire only; no coating on distal end
Wire Sold Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Shelf Life	24 months	24 months

Summary of Non-Clinical Testing:

Design verification and validation testing was conducted following systematic risk assessment in accordance with the FDA-recognized consensus standard ISO 14971 and FDA guidance.

Substantial equivalence of the device, both at the system and component levels (i.e., sterility assurance to the point of care, packaging integrity and shelf-life, biocompatibility, electrical/mechanical safety, and electromagnetic compatibility) has been verified and/or validated in accordance with current FDA-recognized consensus standards and regulatory requirements. The medical device software system has been designed, developed, and verified in compliance with the FDA-recognized consensus standard IEC 62304.

SoundBite® Crossing System – Peripheral (14P) was assessed in the following areas:

- Visual and dimensional inspection
- Simulated use
- Coating integrity
- Tip pull
- Flexibility resistance
- Fracture resistance
- Torque strength
- Tensile strength
- Corrosion resistance
- Torqueability
- Distal temperature
- Tip flexibility
- Catheter qualification
- Lubricity assessment
- Particulate testing

- Shelf-life testing

SoundBite® Console was assessed in the following areas:

- Console Output Stability
- Life-Cycle Testing
- Console and Shipping Container Labels Verification
- Electronics and Software Verification
- ANSI AAMI ES60601-1:2005/(R) 2012 and A1:2012
- IEC 60601-1-2 Edition 4.0 2014-02

Biocompatibility: A full panel of biocompatibility tests was successfully performed in accordance with product classification, under GLP, demonstrating that all utilized materials and methods of construction/processing passed biocompatibility requirements.

Usability: Representative users were included in a summative evaluation. The study confirms that the SoundBite® Crossing System – Peripheral (14P) can be used without serious use errors or problems, for the intended uses under the expected use conditions.

The results from bench testing indicate that the performance characteristics of the SoundBite® Crossing System – Peripheral (14P) are substantially equivalent to the predicate device and do not raise new questions of safety or performance.

Conclusion:

The data submitted with this Special 510(k) premarket notification demonstrate that the SoundBite® Crossing System – Peripheral (14P) is substantially equivalent to the predicate device.