January 17, 2020

SoundBite Medical Solution, Inc.
Mr. Marc-Andre Cote
Director, Regulatory Affairs
2300 Blvd Alfred Nobel
Montreal, QC Canada H4S 2A4

Re: K192211
Trade/Device Name: SoundBite Crossing System - Peripheral
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: December 13, 2019
Received: December 16, 2019

Dear Mr. Cote:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192211

Device Name
SoundBite Crossing System - Peripheral

Indications for Use *(Describe)*
SoundBite™ Crossing System – Peripheral is indicated to facilitate the intra-luminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions. The SoundBite™ Crossing System – 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.

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510(K) Summary

As required by 21 CFR 807.92

Date Prepared: 17 January 2020

Submitted by:
SoundBite Medical Solutions, Inc.
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Trade/Device Name: SoundBite™ Crossing System – Peripheral

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: The CROSSER® S6 System by FlowCardia, Inc. (K092175)

Reference Devices: CROSSER® 14S RX Catheter – The CROSSER® System (K072776)
TruePath™ CTO Device by Boston Scientific Corp. (K140288)
V-18™ ControlWire™ Guidewire by Boston Scientific Corp. (K033742)

Device Description:

The SoundBite™ Crossing System – Peripheral is a recanalization tool, designed to help physicians place conventional guidewires or treatment devices in the intraluminal space beyond chronic total occlusions in the peripheral vasculature. The SoundBite™ Crossing System – Peripheral consists of the reusable mobile SoundBite™ Console, the single-use sterile SoundBite™ Active Wire 18, and their accessories.

The SoundBite™ Console generates controlled mechanical pulses (i.e., shock waves) which are transmitted to the SoundBite™ Active Wire 18 and cause the distal tip of the wire to accelerate axially in a reciprocating motion, acting like a micro-jackhammer.

The SoundBite™ Active Wire 18 is similar in construction to other commercially available CTO crossing wires, with 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 0.46 mm (0.018") and it is 300 cm long, with a working length of 150 cm; the proximal end flares up to a larger diameter for connection to the console. The single-use SoundBite™ Active Wire 18 is supplied sterile with a shelf life of 24 months.

Intended Use / Indications for Use:

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

The SoundBite™ Crossing System – Peripheral is not intended for use in the carotid arteries.

Substantial Equivalence Comparison:

The SoundBite™ Crossing System – Peripheral is substantially equivalent to the predicate device – The CROSSER® S6 System (K092175) – in intended use and indications for use, fundamental technologies, principles of operation, and labeling. Non-clinical bench testing data, and performance data from animal and clinical studies have been submitted to demonstrate that the differences in technological characteristics do not raise different questions of safety and effectiveness. A side-by-side comparison of key device characteristics is presented in the following table:

Device Characteristic	**The CROSSER® S6 System (K092175)**	**SoundBite™ Crossing System – Peripheral**
System components	- AC-powered, mobile CROSSER® Generator with footswitch; - High-frequency transducer; - Single-use CROSSER® S6 Catheter; - FLOWMATE® Injector (optional)	- AC-powered, mobile SoundBite™ Console generator and footswitch; - Single-use SoundBite™ Active Wire 18
Catheter Irrigation	Irrigation port and lumen on catheter. Requires refrigerated saline to control heat generation.	Not required
Mechanism of action	High-frequency mechanical vibrations are propagated through a Nitinol core wire to the Stainless Steel tip of the CROSSER® S6 Catheter.	Mechanical pulses sent along the length of the Titanium alloy SoundBite™ Active Wire 18 cause the distal tip to accelerate axially in a reciprocating (back-and-forth) motion, acting like a micro-jackhammer.
Guidewire Compatibility	No guidewire required	No guidewire required
Catheter/Wire Connection	Connection hub on catheter with transducer coupling and irrigation port	Titanium alloy section reducer for connection to the SoundBite™ Console
Working Length	154 cm or 106 cm	150 cm
Radiopaque Marker	Stainless Steel catheter tip	10 mm radiopaque coil starting at 1.5 mm from the distal tip
Wire/Catheter Shaft Diameter	1.3 mm (0.051”)	0.46 mm (0.018”)

Device Characteristic	The CROSSER® S6 System (K092175)	SoundBite™ Crossing System – Peripheral
Wire/Catheter Tip Diameter	0.6 mm (0.025")	0.29 mm (0.0115")
Wire/Catheter Material	Core: Nitinol Main body: Pebax Tip: Stainless Steel	Titanium alloy
Wire/Catheter Coating	Main body and catheter tip: Hydrophilic coating (material not known)	PTFE coating on main body of the wire only; no coating on distal end
Wire/Catheter Sold Sterile	Yes	Yes
Sterilization Method	Gamma Irradiation	Ethylene Oxide
Shelf Life	Not known	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.

Basic safety and performance 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) have 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.

For device characteristics where objective performance standards and acceptance criteria have not been established, and where direct comparison with the predicate device was not possible, the SoundBite™ Crossing System – Peripheral was compared to commercially available reference devices having substantially similar technological, physiological and anatomical site of use characteristics. The overall acute and chronic safety profile of the proposed system were compared to a reference device in an animal study.

SoundBite™ Crossing System – Peripheral 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 rigors.

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

The results from bench and animal testing indicate that the performance characteristics of the SoundBite™ Crossing System – Peripheral are comparable to the reference devices and do not raise different questions of safety and effectiveness.

Summary of Clinical Testing:

The performance of the SoundBite™ Crossing System – Peripheral was also evaluated under actual clinical conditions in a single-arm clinical study involving 52 patients with documented symptomatic infrainguinal chronic total occlusions (CTO). All CTOs were confirmed angiographically to be 100% occluded.

The SoundBite™ Crossing System – Peripheral has met the primary performance endpoint of technical success in 92.3% of cases (48 of 52 study subjects). Technical success was defined as the ability to facilitate treatment of the target lesions by allowing additional crossing and/or treatment devices to cross the CTO.

In assessing the secondary endpoints, 88.5% (46/52) of subjects had post-procedural patency following successful crossing of the CTO. In 98.1% (51/52) of cases, ≥0.5 cm of any segment of the CTO was crossed. Similarly, in 98.1% (51/52) of cases, ≥1.0 cm of any segment of the CTO was crossed. Furthermore, in 59% (31/52) of cases, the system fully traversed the CTO with entry into the distal lumen without the need for additional guidewires or re-entry devices.

There were no adverse events attributed to the device, as per independent physician adjudication. The study results demonstrate the favorable clinical safety and performance profile of the proposed device.

Conclusion

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