November 19, 2021

Boston Scientific
Mr. Daniel Root
Senior Regulatory Affairs Specialist
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K211080
Trade/Device Name: EkoSonic Endovascular Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEY, KRA
Dated: October 18, 2021
Received: October 20, 2021

Dear Mr. Root:

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)*
K211080

Device Name
EkoSonic Endovascular Device

Indications for Use *(Describe)*
The EkoSonic Endovascular System is indicated for the:
• Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism.
• Infusion of solutions into the pulmonary arteries.
• Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

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.

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Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Daniel Root Three Scimed Place Maple Grove, MN 55311-1566 Phone: 425-395-5820 Email: Daniel.Root@bsci.com
Proprietary Name	EkoSonic™ Endovascular Device
Common Name	Continuous Flush Catheter
Product Code (Primary/Secondary)	QEY, KRA
Classification (Primary/Secondary)	Mechanical Thrombolysis Catheter (21 CFR §870.5150) Catheter, Continuous Flush (21 CFR §870.1210)
Predicate Device	The EkoSonic Endovascular Device is substantially equivalent to another legally marketed device. This predicate device is the EkoSonic Endovascular Device (K191119).
Device Description	The EkoSonic Endovascular System consists of an EkoSonic Endovascular Device and EKOS Control Unit (Control Unit 4.0 or PT-3B and Connector Interface Cables). The EkoSonic Endovascular Device consists of a single-use, disposable infusion catheter with removable ultrasound core. The infusion catheter contains multiple side holes distributed over the length of the treatment zone. The ultrasound core contains up to 30 ultrasound elements, evenly spaced over the treatment zone. Thermal sensors in the treatment zone monitor catheter temperature. The Control System generates and controls the delivery of radiofrequency energy to the ultrasound core while monitoring and controlling the temperature of the treatment zone.
Indications for Use/ Intended Use	The EkoSonic Endovascular System is indicated for the: • Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
Device Technology Characteristics and Comparison to Predicate Device	The EkoSonic Endovascular Device incorporates the following changes from the predicate EkoSonic Endovascular Device (K191119): an updated luer design that is ISO 80369-7 compliant; luer material change to a Cyrolite® Polymer; and updated packaging and labeling appropriate to be consistent with legal manufacturer branding.

Characteristic	EkoSonic Endovascular Device (Subject Device)	EkoSonic Endovascular Device (Predicate Device)
510(k) Number	K211080	K191119
Product Code	QEY, KRA	QEY, KRA
Indications for Use	The EkoSonic Endovascular System [with Control Unit] is indicated for the: • Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.	The EkoSonic Endovascular System [with Control Unit] is indicated for the: • Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
Principle of Operation	The EkoSonic Endovascular System [EkoSonic Endovascular Device with Control Unit] employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.	The EkoSonic Endovascular System [EkoSonic Endovascular Device with Control Unit] employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.
Infusion Hole Pattern	Multiple side-holes	Multiple side-holes
Catheter Working Length	106 cm or 135 cm	106 cm or 135 cm
Treatment Zone Length	6 cm – 50 cm	6 cm – 50 cm
Compatible Guide Wire	0.035”	0.035”
Outer Diameter	5.4 Fr	5.4 Fr
Placement Mode	Percutaneous/endovascular	Percutaneous/endovascular
Packaged Sterile	Yes – EkoSonic Endovascular Device	Yes – EkoSonic Endovascular Device
Single-Use Disposable	Yes – EkoSonic Endovascular Device	Yes – EkoSonic Endovascular Device
Materials Biocompatible	Yes – EkoSonic Endovascular Device	Yes – EkoSonic Endovascular Device

Characteristic	EkoSonic Endovascular Device (Subject Device)	EkoSonic Endovascular Device (Predicate Device)
Radiopaque Markers	Markerbands on the Infusion Catheter (IC) are radiopaque The Ultrasonic Core (USCO ultrasound elements are also radiopaque	Markerbands on the IC are radiopaque The USC ultrasound elements are also radiopaque
Mechanism of Action	Ultrasound	Ultrasound
Energy Source	R/F electrical from CU converted to ultrasound	R/F electrical from CU converted to ultrasound
Ultrasound Transducer(s) in Catheter	6 to 30	6 to 30
Acoustic Characteristics	Frequency = 2.05 – 2.35 MHz	Frequency = 2.05 – 2.35 MHz
Maximum Output Power Limit	Power is available for ~100W Pulses. The power output is limited by software to ~50W.	Power is available for ~100W Pulses. The power output is limited by software to ~50W.
Maximum EkoSonic Device Temperature	Temperature monitoring, feedback and control system limits the surface temperature of the IC to 43°C during operation.	Temperature monitoring, feedback and control system limits the surface temperature of the IC to 43°C during operation.
Luer Design	ISO 80369-7 Compliant	ISO 594 Compliant
Luer Material	Cyrolite® Polymer (acrylic copolymer)	Polycarbonate

Non-Clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing, including bench-top performance evaluations and biological safety. **Bench Testing**: Bench testing was performed to evaluate physical integrity, functionality, and performance of the catheter. Performance criteria includes: catheter tensile strengths, freedom from leak, and burst pressure. **Biological Safety Testing**: Biocompatibility testing in accordance with ISO 10993-1, microbial assessments including bioburden and endotoxin, and pyrogenicity and sterility assurance testing show the device has acceptable biological safety for its intended use.
Clinical Testing	Performance testing from clinical studies is not required to demonstrate substantial equivalence of EkoSonic Endovascular Device.
Conclusion	Based on the indications for use, technological characteristics, and performance testing, EkoSonic Endovascular Device has been shown to be appropriate for its intended use and is considered to be substantially equivalent to EkoSonic Endovascular Device, K191119.