December 14, 2021

Boston Scientific Corporation
Ambreen Athar
Regulatory Affairs, Principal Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K213422
Trade/Device Name: EkoSonic Endovascular Device, EKOS+ 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 Ambreen Athar:

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)*
K213422

Device Name
EkoSonic Endovascular Device
EKOS+ Endovascular Device

Indications for Use *(Describe)*

The EkoSonic™ Endovascular System is indicated for the:
• Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis
• Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.

The EKOS+ Endovascular System is indicated for the:
• Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis
• Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or 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.

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."

Premarket Notification 510(k) Summary for K213422

I. Submitter

Boston Scientific Corporation
Three Scimed Place
Maple Grove, MN 55311

Phone: 763.995.8171

Contact Person: Ambreen Athar
Alternate Contact Person: Brent Hathcock

Date Prepared: December 13, 2021

II. Devices

Proprietary Name:	EkoSonic Endovascular Device
Common or Usual Name:	Continuous Flush Catheter
Primary Classification Name:	Mechanical Thrombolysis Catheter (21 CFR §870.5150)
Primary Product Code:	QEY
FDA Panel/Device Class:	Cardiovascular; Class II
Secondary Classification Name:	Catheter, Continuous Flush (21 CFR §870.1210)
Secondary Product Code:	KRA
FDA Panel/Device Class:	Cardiovascular; Class II

Proprietary Name:	EKOS+ Endovascular Device
Common or Usual Name:	Continuous Flush Catheter
Primary Classification Name:	Mechanical Thrombolysis Catheter (21 CFR §870.5150)
Primary Product Code:	QEY
FDA Panel/Device Class:	Cardiovascular; Class II
Secondary Classification Name:	Catheter, Continuous Flush (21 CFR §870.1210)
Secondary Product Code:	KRA
FDA Panel/Device Class:	Cardiovascular; Class II

III. Predicate Devices

The proposed modification is to the Indications For Use for both the EkoSonic Endovascular Device (K191119) and EKOS PE Endovascular Device (K200648). The modification to the indications is to include Deep Vein Thrombosis (DVT). A systematic literature review is presented to support the appropriateness of the change. There is no change to the design or manufacture of the device as a result of this change, therefore, the predicate devices are the current versions of the legally marketed devices. The predicate devices will be EkoSonic Endovascular Device (K191119) and the EKOS PE Endovascular Device (K200648).

No reference devices were used in this notification.

IV. Device Description

EkoSonic Endovascular Device –
The sterile, single-use EkoSonic Endovascular Device consists of an Infusion Catheter (IC) and an Ultrasonic Core (USC). The USC fits within the central lumen of the IC. Together, they are used to deliver physician-specified fluids and ultrasound energy to the treatment zone.

EKOS+ Endovascular Device –
The sterile, single-use EKOS+ Endovascular Device consists of an Infusion Catheter (IC),and an Ultrasonic Core (USC). The USC fits within the central lumen of the IC. Together, they are used to deliver physician-specified fluids and ultrasound energy to the treatment zone.

V. Proposed Intended Use/Indications for use

The EkoSonic™ Endovascular System is indicated for the:

- Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis
- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.

The EKOS+ Endovascular System is indicated for the:

- Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis
- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.

VI. Comparison of Technological Characteristics with the Predicate Devices

	PREDICATE DEVICES		SUBJECT DEVICES	
	EkoSonic Endovascular Device (Predicate Device)	**EKOS PE Endovascular Device with CU4.0 (Predicate Device)**	**EkoSonic Endovascular Device (Subject Device)**	**EKOS+ Endovascular Device (Subject Device)**
510(k) Number	K191119	K200648	To be assigned	To be assigned
Product Code	QEY, KRA	QEY, KRA	QEY, KRA	QEY, KRA
Product Name	EkoSonic Endovascular Device	EKOS PE Endovascular Device	EkoSonic Endovascular Device	EKOS+ Endovascular Device

	PREDICATE DEVICES		SUBJECT DEVICES	
	EkoSonic Endovascular Device (Predicate Device)	**EKOS PE Endovascular Device with CU4.0 (Predicate Device)**	**EkoSonic Endovascular Device (Subject Device)**	**EKOS+ Endovascular Device (Subject Device)**
Indications for Use	The EkoSonic Endovascular Device with CU4.0 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 EKOS PE Endovascular System [with CU4.0] 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 is indicated for the: • Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.	The EKOS+ Endovascular System is indicated for the: • Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.
Principle of Operation	The EkoSonic Endovascular System employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.	The EKOS PE Endovascular System [EKOS PE Endovascular Device with CU4.0] employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.	The EkoSonic Endovascular System employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.	The EKOS+ Endovascular System employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.
Infusion Hole Pattern	Multiple side-holes	Multiple side-holes	Multiple side-holes	Multiple side-holes
Catheter Working Length	106 cm or 135 cm	106 cm or 135 cm	106 cm or 135 cm	106 cm or 135 cm
Treatment Zone Length	6 cm – 50 cm	8 cm — 20 cm	6 cm – 50 cm	8 cm — 20 cm
Compatible Guide Wire	0.035”	0.035”	0.035”	0.035”
Outer Diameter	5.4 Fr	7.7 Fr	5.4 Fr	7.7 Fr
Placement Mode	Percutaneous/endovascular	Percutaneous/endovascular	Percutaneous/endovascular	Percutaneous/endovascular
Packaged Sterile	Yes – EkoSonic Endovascular Device	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovascular Device	Yes – EKOS+ Endovascular Device

	PREDICATE DEVICES		SUBJECT DEVICES	
	EkoSonic Endovascular Device (Predicate Device)	**EKOS PE Endovascular Device with CU4.0 (Predicate Device)**	**EkoSonic Endovascular Device (Subject Device)**	**EKOS+ Endovascular Device (Subject Device)**
Single-Use Disposable	Yes – EkoSonic Endovascular Device	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovascular Device	Yes – EKOS+ Endovascular Device
Materials Biocompatible	Yes – EkoSonic Endovascular Device	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovascular Device	Yes – EKOS+ Endovascular Device
Radiopaque Markers	Yes on IC USC ultrasound elements are radiopaque	Yes on IC USC ultrasound elements are radiopaque	Yes on IC USC ultrasound elements are radiopaque	Yes on IC USC ultrasound elements are radiopaque
Mechanism of Action	Ultrasound	Ultrasound	Ultrasound	Ultrasound
Energy Source	R/F electrical from CU converted to ultrasound	R/F electrical from CU converted to ultrasound	R/F electrical from CU converted to ultrasound	R/F electrical from CU converted to ultrasound
Ultrasound Transducer(s) in Catheter	6 to 30	8 to 20	6 to 30	8 to 20
Acoustic Characteristics	Frequency = 2.05 – 2.5 MHz	Frequency = 1.58-2.00 MHz	Frequency = 2.05 – 2.5 MHz	Frequency = 1.58-2.00 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.	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.	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.

There are no device modifications (individually or cumulatively) to the subject devices that impact the technological characteristics of the devices since the last 510(k) submission including:

- Product specification requirements
- Raw material composition or constituents
- Product chemical composition or the physical and chemical properties
- Device packaging (with the exception of BSC branding on the labels)

The only change is to the indications for use to include the DVT as a treatment and a change to the trade name of EKOS PE to EKOS+.

VII. Performance Data

Device testing was not required to support the change to the indications for use changes. There are no changes to the device technological characteristics. The devices are, therefore, substantially equivalent to the predicate device.

VIII. Clinical Data

A systematic literature review, including data from the ACCESS-PTS trial and CAVA studies, were used to support the inclusion of DVT to the indications for use with both the EkoSonic Endovascular and EKOS+ Endovascular devices.

IX. Conclusions

The EkoSonic Endovascular Device and the EKOS+ Endovascular Device are substantially equivalent to the predicate devices. The expansion to the indications for use and the change to the trade name do not impact the technological characteristics for the system.