November 22, 2021

BTG International, Inc.
Joshua Kim
Sr. Regulatory Affairs Specialist
11911 North Creek Parkway S
Bothell, Washington 98011

Re: K191119
Trade/Device Name: EkoSonic Endovascular Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Joshua Kim:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 23, 2019. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.11.22 13:41:54 -05'00'

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

August 23, 2019

BTG International, Inc.
Joshua Kim
Sr. Regulatory Affairs Specialist
11911 North Creek Parkway S
Bothell, Washington 98011

Re: K191119
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: April 24, 2019
Received: April 26, 2019

Dear Mr. Joshua Kim:

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 W. O'connell -S

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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)*
K191119

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
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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 K191119

I. Submitter

EKOS Corporation, Inc.
11911 North Creek Parkway S
Bothell, WA 98011

Phone: 425-415-3114
Fax: 425-415-3105

Contact Person: Joshua Kim
Date Prepared: August 22, 2019

II. Device

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

III. Predicate Devices

The EkoSonic Endovascular Device is substantially equivalent to another legally marketed device. This predicate device is the EkoSonic MACH 4 Endovascular Device, cleared as part of the EkoSonic Endovascular System with the EKOS Control Unit (model PT-3B [K182324] and CU4.0 [K183361]).

No reference devices were used in this notification.

IV. Device Description

The EkoSonic Endovascular System consists of an EkoSonic Endovascular Device and the Control System (Control Unit 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.

This notification is being made due to the modification of the MSD hub portion of the EkoSonic Endovascular Device.

V. Intended Use/Indications for 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.

VI. Comparison of Technological Characteristics with the Predicate Device

	EkoSonic Endovascular Device with Control Unit 4.0 (Predicate Device)	**EkoSonic Endovascular Device with Control Unit PT-3B (Predicate Device)**	**EkoSonic Endovascular Device (Subject Device)**
510(k) Number	K183361	K182324	K191119
Product Code	KRA	KRA	QEY/KRA (Primary/Secondary)
Indications for Use	The EkoSonic Endovascular Device with CU 4.0 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 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 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 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 EkoSonic Endovascular System [EkoSonic Endovascular Device with EKOS Control Unit] 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
Catheter Working Length	106 cm or 135 cm	106 cm or 135 cm	106 cm or 135 cm
Treatment Zone Length	6 cm – 50 cm	6 cm – 50 cm	6 cm – 50 cm

	EkoSonic Endovascular Device with Control Unit 4.0 (Predicate Device)	EkoSonic Endovascular Device with Control Unit PT-3B (Predicate Device)	EkoSonic Endovascular Device (Subject Device)
Compatible Guide Wire	0.035"	0.035"	0.035"
Outer Diameter	5.4 Fr	5.4 Fr	5.4 Fr
Placement Mode	Percutaneous/endovascular	Percutaneous/endovascular	Percutaneous/endovascular
Packaged Sterile	Yes – EkoSonic Device	Yes – EkoSonic Device	Yes – EkoSonic Device
Single-Use Disposable	Yes – EkoSonic Device	Yes – EkoSonic Device	Yes – EkoSonic Device
Materials Biocompatible	Yes – EkoSonic Device	Yes – EkoSonic Device	Yes – EkoSonic Device
Radiopaque Markers	Yes on IDDC MSD ultrasound elements are radiopaque	Yes on IDDC MSD ultrasound elements are radiopaque	Yes on IDDC MSD ultrasound elements are radiopaque
Mechanism of Action	Ultrasound	Ultrasound	Ultrasound
Energy Source	R/F electrical from CU 4.0 converted to ultrasound	R/F electrical from PT-3B converted to ultrasound	R/F electrical from CU converted to ultrasound
Ultrasound Transducer(s) in Catheter	6 to 30	6 to 30	6 to 30
Acoustic Characteristics	Frequency = 2.0 – 2.5 MHz	Frequency = 2.0 – 2.5 MHz	Frequency = 2.0 – 2.5 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.
Maximum EkoSonic Device Temperature	Temperature monitoring, feedback and control system limits the surface temperature of the IDDC to 43°C during operation.	Temperature monitoring, feedback and control system limits the surface temperature of the IDDC to 43°C during operation.	Temperature monitoring, feedback and control system limits the surface temperature of the IDDC to 43°C during operation.

The device modifications described in the notification do not affect the intended use, indications for use or the technological characteristics for the EkoSonic Endovascular System (EkoSonic Endovascular Device with Control Unit).

VII. Performance Data

Testing has confirmed that the EkoSonic Endovascular Device functions as intended and is substantially equivalent to the predicate device.

Product Specification	Purpose	EkoSonic Endovascular Device (Subject Device)	
		T = 0	Artificially Aged (T=3 Years)
Device Level Testing			
Tensile Strength	The proposed MSD hub change redesigns the shaft-to-cable and Luer-to-cover joints. It replaces the shaft-to-cable lap joint with a soldered PCB connection and the Luer-to-cover epoxy joint with a snap-on cover.	Pass	Pass
Catheter Interlock	The proposed MSD hub change redesigns the catheter interlock by replacing the epoxy which served as the watertight seal with a copolyester overmold. The overmold fills the void between the Luer barb and the snap-on cover.	Pass	Pass
Impedance	The proposed MSD hub change redesigns the connection between the shaft-to-cable connection which is the RF energy path from the CIC to the transducers.	Pass	Pass
Resonant Frequency		Pass	Pass
Luers	The prosposed MSD hub change redesigned the Luer barb to facilitate the use of the snap-on cover. The design change did not affect any other aspect aside from the cover interation.	Pass	Pass
Electrical Isolation	The proposed MSD hub change redesigns the leakage current pathway from the connector to external fluid.	Pass	Pass
Sterilization	The device undergoes shipping, storage, sterilization, and shelf life simulation to provide representative test articles for design verification testing.	Pass	Pass
Shipping		Pass	Pass
Storage		Pass	Pass
Shelf Life		Pass	Pass
Burst Strength	The proposed MSD hub change redesigns the Luer-to-cover interface and affects resistance to high static pressure.	Pass	Pass
Fluid Immersion	The proposed MSD hub change replaces the primary seal with and overmold. As such, design verification testing assessed continuity before and after fluid immersion.	Pass	Pass
Bending Force	The proposed MSD hub change replaces the Luer and strain relief with a new Luer bard and snap-on cover. As such, EKOS assessed the bending force of snap-on cover.	Pass	Pass

Product Specification	Purpose	EkoSonic Endovascular Device (Subject Device)	
		T = 0	Artificially Aged (T=3 Years)
System Level Testing			
System Integration with PT-3B	The proposed MSD hub changes affect the connection between the MSD and the Control System.	Pass	N/A. Samples were not aged for system integration validation testing.
System Integration with CU4.0		Pass	

Performance standards have not been promulgated for Mechanical Thrombolysis or Continuous Flush Catheters.

VIII. Conclusions

The EkoSonic Endovascular Device is substantially equivalent to the predicate devices. The modifications to the EkoSonic Endovascular Device do not affect the intended use or the technological characteristics for the system.