November 22, 2021

BTG International, Inc.
Benjamin Hornsey
Regulatory Affairs Manager
11911 N Creek Pkwy S
Bothell, Washington 98011

Re: K183361
Trade/Device Name: EkoSonic Endovascular Device with Control Unit 4.0
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Benjamin Hornsey:

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 April 5, 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 13:40:42 -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

April 5, 2019

BTG International, Inc.
Benjamin Hornsey
Regulatory Affairs Manager
11911 N Creek Pkwy S
Bothell, Washington 98011

Re: K183361
Trade/Device Name: EkoSonic Endovascular Device with Control Unit 4.0
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 5, 2019
Received: March 6, 2019

Dear Mr. Hornsey:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Hajira F. Ahmad -S
Digitally signed by Hajira F. Ahmad -S
Date: 2019.04.05 14:01:06 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K183361

Device Name
EkoSonic Endovascular Device with Control Unit 4.0

Indications for Use *(Describe)*
The EkoSonic Endovascular Device with Control Unit 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.

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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K183361 510(k) Summary

I. Submitter

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

Phone: 425-415-3143
Fax: 425-415-3105

Contact Person: Benjamin Hornsey
Date Prepared: December 3, 2018

II. Device

Proprietary Name:	EkoSonic™ Endovascular Device with Control Unit 4.0
Common or Usual Name:	Continuous Flush Catheter
Classification Name:	Catheter, Continuous Flush (21 CFR §870.1210)
Product Code:	KRA

Continuous Flush Catheters have been classified by the FDA Cardiovascular Panel as Class II.

III. Predicate Devices

The EkoSonic Endovascular Device with CU 4.0 (CU 4.0) is substantially equivalent to another legally marketed device. This predicate device is the EKOS EkoSonic Endovascular Device with CU 4.0 (K162771).

No reference devices were used in this submission.

IV. Device Description

The EkoSonic Endovascular Device with CU 4.0 consists of an EkoSonic Endovascular Device and the Control System 4.0 (Control Unit 4.0 and Connector Interface Cables). The EkoSonic Endovascular Device consists of a 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 4.0 generates and controls the delivery of radiofrequency energy to the ultrasound core while monitoring and controlling the temperature of the treatment zone.

It is the modifications to the Control System 4.0 that are the subject of this submission.

K183361 510(k) Summary

V. Intended Use/Indications for use

The EkoSonic Endovascular Device with Control Unit 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.

VI. Comparison of Technological Characteristics with the Predicate Device

	EkoSonic Endovascular Device with CU 4.0 (Subject Device)	**EkoSonic Endovascular Device with CU 4.0 (Predicate Device)**
510(k) Number	K183361	K162771
Product Code	KRA	KRA
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 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.
Principle of Operation	The EkoSonic Endovascular Device with CU 4.0 employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.	The EkoSonic Endovascular Device with CU 4.0 employs ultrasound to facilitate the delivery of thrombolytic agents into vascular blood clots.
Software Version	01.02.02	01.00.05
Battery Version	8742-003	6841-002
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

K183361 510(k) Summary

	EkoSonic Endovascular Device with CU 4.0 (Subject Device)	EkoSonic Endovascular Device with CU 4.0 (Predicate Device)
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 Device	Yes – EkoSonic Device
Single-Use Disposable	Yes – EkoSonic Device	Yes – EkoSonic Device
Materials Biocompatible	Yes – EkoSonic Device	Yes – EkoSonic Device
Radiopaque Markers	Yes on IDDC MSD ultrasound elements are radiopaque	Yes on IDDC MSD ultrasound elements are radiopaque
Mechanism of Action	Ultrasound	Ultrasound
Energy Source	R/F electrical from CU 4.0 converted to ultrasound	R/F electrical from CU 4.0 converted to ultrasound
Ultrasound Transducer(s) in Catheter	6 to 30	6 to 30
Acoustic Characteristics	Frequency = 2.0 – 2.5 MHz	Frequency = 2.0 – 2.5 MHz
Battery Backup	Internal, lithium-ion backup battery	Internal, lithium-ion backup battery
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 IDDC to 43ºC during operation.	Temperature monitoring, feedback and control system limits the surface temperature of the IDDC to 43ºC during operation.

The device modifications described in the submission do not affect the intended use, indications for use or the technological characteristics for the EkoSonic Endovascular System.

VII. Performance Data

Testing has confirmed that the EkoSonic Endovascular Device with CU 4.0 functions as intended and is substantially equivalent to the predicate device.

Hardware Testing Performed	
Secondary Cell Battery Tests	Pass
Reliability Prediction	Pass
Battery Hardware Design Verification	Pass
Electrical Safety	Pass
Hardware Inspection	Pass
EMC/EMI	Pass
RF Board Hardware Tests	Pass
System Integration	Pass
CIC Hardware Tests	Pass
Shipping Package Tests	Pass
Design Verification Hardware Tests	Pass
UI Board Hardware Tests	Pass
Environmental Tests	Pass
Power Management Module Tests	Pass
Short Circuit Response	Pass
Patched Fastener Design Verification	Pass
EkoSonic Device Reliability	Pass

Software Testing Performed	
Periodic Self-Test	Pass
User Interface	Pass
Firmware Upgrade	Pass
Event Logging	Pass
System Connect Validation	Pass
Single Channel RF	Pass
Graphing	Pass
Device Compatibility	Pass
Dual Channel RF	Pass
Therapy Support	Pass
System Startup	Pass
Processor Communication	Pass
Constant Parameter	Pass
Source Code Inspection	Pass
AC and Battery Power	Pass

Performance standards have not been promulgated for Continuous Flush Catheters.

VIII. Conclusions

The EkoSonic Endovascular Device with CU 4.0 is substantially equivalent to the predicate device. The modifications to the Control System 4.0 do not affect the intended use or the technological characteristics for the system and do not raise new questions of safety or effectiveness.