DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2017

BTG International, Inc.
Curtis Jensen
Senior Regulatory Affairs Associate
11911 N Creek Pkwy S
Bothell, Washington 98011

Re: K162771
Trade/Device Name: EkoSonic Endovascular System with Control Unit 4.0
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 18, 2017
Received: January 23, 2017

Dear Curtis Jensen:

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. 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.

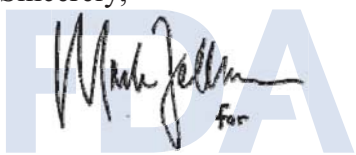
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162771

Device Name
EkoSonic Endovascular System with Control Unit 4.0

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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Section 5: 510(k) Summary

I. Submitter

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

Phone: 425-415-3122
Fax: 425-415-3105

Contact Person: Curtis Jensen
Date Prepared: September 30, 2016

II. Device

Proprietary Name:	EkoSonic® Endovascular System 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 System with Control Unit 4.0 (CU 4.0) is substantially equivalent to another legally marketed device. This predicate device is the EKOS EkoSonic Endovascular System with the EkoSonic Control Unit (PT-3B) (K140151).

This predicate device has been subject to one design-related Class II recall. Recall Z-1752-2008 was determined to be Software Design related. The device design used as a predicate device for this submission represents the most current software and hardware design.

No reference devices were used in this submission.

IV. Device Description

The EkoSonic Endovascular System consists of an EkoSonic Device and the Control Unit 4.0 (CU 4.0). The EkoSonic 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 CU 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 unit that are the subject of this submission.

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 Devices

	Predicate Devices	**Proposed Device**
Device Name	EkoSonic Endovascular System with PT3-B	EkoSonic Endovascular System with CU 4.0
510(k) Number(s)	K140151 – Amendment 002	To be assigned
Product Code	KRA	KRA **(This is equivalent to the predicate device)**
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.	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. **(These are is equivalent to the predicate device)**
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. **(This is equivalent to the predicate device)**

	Predicate Devices	Proposed Device
Energy Source	The EkoSonic Control Unit (PT-3B) provides the power and user interface for operator control.	The upgraded EkoSonic Control Unit (CU 4.0) provides the power and user interface for operator control. **(This is equivalent to the predicate device)**
Battery Backup	No internal battery backup	Internal, lithium-ion backup battery
Maximum Output Power Limit	Power limited to ~50 W Pulses	Power is available for ~100W Pulses. The power output is limited by software to ~50W, which is identical to the predicate device.
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. **(This is equivalent to the predicate device)**
Accessories	The predicate control unit is designed to provide electrical energy to drive the ultrasound transducers in EKOS Corporation catheters.	The Control Unit 4.0 is designed to provide electrical energy to drive the ultrasound transducers in EKOS Corporation catheters. **(This is equivalent to the predicate device)**
Materials	Chassis and Front Panel: Die Cast and sheet Aluminum, Painted	Chassis – Sheet aluminum, powder coated or clear anodized Front Panel – Black Powder-coated Aluminum

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

VII. Performance Data

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

Hardware Testing Performed	
System Tip Test	Pass
Secondary Cell Battery Test	Pass
Reliability Prediction	Pass
Battery Life Prediction	Pass
Electrical Safety	Pass
Hardware Inspection	Pass
EMC/EMI	Pass
RF Board Tests	Pass
System Integration	Pass
CIC Hardware Tests	Pass
Shipping Package Tests	Pass
Design Verification Hardware Tests	Pass
UI Board Hardware Tests	Pass

Hardware Testing Performed	
Environmental Tests	Pass
Power Management Module Tests	Pass

Software Testing Performed	
Periodic Self-Test	Pass
User Interface	Pass
Firmware Upgrade	Pass
Event Logging	Pass
System Connect Validation	Pass
Single Cannel RF	Pass
Graphing	Pass
Device Compatibility	Pass
Dual Channel RF	Pass
Therapy Support	Pass
Workflow	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 System with Control Unit 4.0 is substantially equivalent to the predicate device. The modifications in the control unit do not affect the intended use or the technological characteristics for the system and do not raise different questions of safety or effectiveness.