August 17, 2020

EKOS Corporation
Mr. Joshua Kim
Sr. Regulatory Affairs Specialist
11911 North Creek Parkway S
Bothell, Washington 98011

Re: K200648
Trade/Device Name: EKOS PE Endovascular Device with Control System 4.0
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEY, KRA
Dated: July 17, 2020
Received: July 20, 2020

Dear Mr. 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,

For

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)*
K200648

Device Name
EKOS PE Endovascular Device with Control Unit 4.0

Indications for Use *(Describe)*
The EKOS PE 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.

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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EKOS

Premarket Notification 510(k) Summary for K200648

I. Submitter

EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

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

Contact Person: Joshua Kim
Date Prepared: August 17, 2020

II. Device

Proprietary Name:	EKOS™ PE Endovascular Device with CU4.0
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 EKOS PE Endovascular Device with CU4.0 is substantially equivalent to another legally marketed device. This predicate device is the EkoSonic Endovascular Device with CU4.0 (K183361).

No reference devices were used in this notification.

IV. Device Description

The EKOS PE Endovascular System consists of an EKOS PE Endovascular Device and CU4.0 (Control Unit 4.0 and Connector Interface Cables). The EKOS PE 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 20 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.

V. Intended Use/Indications for use

The EKOS PE 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

	EKOS PE Endovascular Device with CU4.0 (Subject Device)	**EkoSonic Endovascular Device with CU4.0 (Predicate Device)**
510(k) Number	K200648	K183361
Product Code	QEY, KRA	KRA
Indications for Use	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 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.
Principle of Operation	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.
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	8 cm — 20 cm	6 cm – 50 cm

	EKOS PE Endovascular Device with CU4.0 (Subject Device)	EkoSonic Endovascular Device with CU4.0 (Predicate Device)
Compatible Guide Wire	0.035"	0.035"
Outer Diameter	7.7 Fr	5.4 Fr
Placement Mode	Percutaneous/endovascular	Percutaneous/endovascular
Packaged Sterile	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovascular Device
Single-Use Disposable	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovascular Device
Materials Biocompatible	Yes – EKOS PE Endovascular Device	Yes – EkoSonic Endovsacular 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 converted to ultrasound	R/F electrical from CU converted to ultrasound
Ultrasound Transducer(s) in Catheter	8 to 20	6 to 30
Acoustic Characteristics	Frequency = 1.58-2.00 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 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 EKOS PE Endovascular System (EKOS PE Endovascular Device with CU4.0).

VII. Performance Data

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

Table 1: Testing Overview Supporting the EKOS PE Endovascular System

Product Specification	Purpose	EKOS PE Endovascular Device (Subject Device)	
		T = 0	Accelerated Aged (T=3 Years)
Physical Dimensions	Verified dimensional compatibility and stability with the MSD and DDC.	Pass	Pass
Tip Shape	Verified tip conformity to ISO 10555-1 requirements.	Pass	Pass
Kink Resistance	Verified device can be used within the target vasculature.	Pass	Pass
Tensile Strength	Verified device conformity to ISO 10555-1 requirements.	Pass	Pass
Electrical Safety	Verified device conformity IEC 60601-1 and IEC 60601-1-2 requirements.	Pass	Pass
Acoustic Characteristics	Verified device met specified acoustic design requirements.	Pass	Pass
Radiopacity	Verified device can be viewed under standard imaging techniques.	Pass	Pass
Pressure Resistance	Verified device lumens conformity to ISO 10555-1.	Pass	Pass
Temperature Sensing	Verified the device temperature sensors met specified design and functional requirements.	Pass	Pass
Functional Life	Verified device met specified functional life requirements.	Pass	Pass
Biocompatibility	Verified the device met biocompatibility requirements per ISO 10993-1.	Pass	Pass
Sterilization	Verified the device met sterilization requirements per ISO 11135.	Pass	Pass
Shelf Life	Verified the device met functional requirements after a 3-year shelf life.	N/A.	Pass
System Integration with CU4.0	Verified the device integrates with the control unit, specifically, its acoustic protocol and enabled temperature safety features.	Pass	N/A.

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

VIII. Conclusions

The EKOS PE Endovascular Device with CU4.0 is substantially equivalent to the predicate devices. The modifications to the EkoSonic Endovascular Device with CU4.0 do not affect the intended use or the technological characteristics for the system.