January 7, 2022

EKOS Corporation
Jocelyn Kersten
Regulatory Affairs Manager
22030 20th Avenue SE, Suite 101
Bothell, Washington 98021

Re: K033214
Trade/Device Name: EKOS Peripheral Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

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 October 14, 2003. 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: 2022.01.07 13:30:30 -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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2003

EKOS Corp.
c/o Ms. Jocelyn Kersten
22030 20th Ave SE, Suite 101
Bothell, WA 98021

Re: K033214
EKOS Peripheral Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: October 2, 2003
Received: October 3, 2003

Dear Ms. Kersten:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3. Indication for Use

510(k) Number K033214

Device Name EKOS Peripheral Infusion System

Indications for Use The EKOS Peripheral Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033214

K033214

OCT 1 4 2003

Section 4. 510(k) Summary

General Provisions	Submitter's Name and Address	EKOS Corporation 22030 20th Ave. SE Suite 101 Bothell, WA 98021
	Contact Person	Jocelyn Kersten 425-482-1108 425-482-1109 (fax) jkersten@EKOSCORP.com
	Classification Name	Catheter, Continuous Flush (KRA)
	Common or Usual Name	Continuous Flush Catheter
	Proprietary Name	EKOS Peripheral Infusion System
Name of Predicate Device	Predicate Device	510(k) Reference No.
	EKOS Peripheral Infusion System	K030637
Device Description	The system consists of a disposable infusion/ultrasound catheter and an instrument that generates and controls the delivery of energy to the catheter. The catheter contains a single ultrasound transducer, located at the distal tip, a thermal sensor and a distal end hole for placement over a guide wire and fluid infusion.	
Intended Use	The EKOS Peripheral Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.	
Summary of Technological Characteristics	The proposed EKOS Peripheral Infusion System is similar in construction and materials to the previously cleared EKOS Peripheral Infusion System.	
Test Summary	The proposed EKOS Peripheral Infusion System is considered to be substantially equivalent to the currently marketed EKOS Peripheral Infusion System based on a comparison of the intended uses and designs and results of the testing and evaluations performed.	