510(k) Summary

APR 22 2008

Applicant Name: EKOS Corporation

Address: 11911 North Creek Parkway South
Bothell, WA 98011

Contact Person: Jocelyn Kersten
Vice President, Quality Assurance, Regulatory and Clinical Affairs

Telephone: (425) 415-3132

Fax: (425) 415-3102

Device: EndoWave™ Infusion System

Classification: CFR 870.1210 – Continuous Flush Catheter

Panel: Cardiovascular

Product Code: KRA

Intended Use: The EndoWave™ Infusion System is intended for the infusion of solutions into the pulmonary arteries.

The safety and effectiveness of the EKOS EndoWave™ Infusion system for thrombolytic therapy administration in pulmonary embolus have not been established. In particular, the ultrasound energy delivered by the EndoWave system is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli.

Device Description: The EndoWave™ Infusion System is an infusion catheter system designed to deliver fluids via a multi sidehole catheter. The fluid is dispersed via multiple ultrasound transducers distributed linearly along the length of an ultrasound core which is placed into the center lumen of the catheter. This device is intended to deliver physician-specified agents or fluids into the peripheral vasculature.

Predicate Basis: The EndoWave™ Infusion System is substantially equivalent to other legally marketed devices. These devices include

1. EKOS EndoWave Infusion System (*EKOS Corporation*, **K071933**, **K072507**)
2. EKOS NeuroWave Infusion System (*EKOS Corporation*, **K062508, K063620**)
3. Edwards Swan-Ganz Standard Thermodilution Pulmonary Artery Catheter, (*Edwards Lifesciences*, **K014054**)
4. *Z*-Med II-X, (*NuMED*, Inc., **K003052,K011557, K030589**)

Performance: EKOS has conducted preclinical bench and animal studies with the

EndoWave™ Infusion System. These studies demonstrate that the performance of the EndoWave™ Infusion System meets its design specifications for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

EKOS Corporation
c/o Ms. Jocelyn Kersten
11911 North Creek Parkway South
Bothell, WA 98011

Re: K073166
EKOS EndoWave Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: January 18, 2008
Received: January 22, 2008

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear immediately following the indication for use in the device's labeling:

> The safety and effectiveness of the EKOS EndoWave™ Infusion system for thrombolytic therapy administration in pulmonary embolus have not been established. In particular, the ultrasound energy delivered by the EndoWave system is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

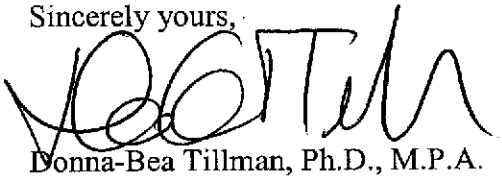
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.10 Indications for Use Statement

EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

Indications for Use Statement

510(k) Number (if known): K073166

Device Name: EndoWave™ Infusion System

Indications for Use:

The EndoWave™ Infusion System is intended for the infusion of solutions into the pulmonary arteries.

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Prescription Use X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073166