K062508

DEC - 5 2006

Section 4. 510(k) Summary

General Provisions

Submitter's Name and Address:	EKOS Corporation 11911 North Creek Pkwy South Bothell, WA 98011
Contact Person:	Jocelyn Kersten 425-415-3132 425-415-3101 (fax) jkersten@EKOSCORP.com
Classification Name:	Ultrasound, Infusion, System (NUI)
Common or Usual Name:	Ultrasound Infusion Catheter
Proprietary Name:	NeuroWave Micro-Infusion System
Name of Predicate Device:	NeuroWave Micro-Infusion System
510(k) Reference No.:	K060084 K053437 K053432

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 Micro- Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

The EKOS Micro- Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro- Infusion System may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.

Summary of Technological Characteristics
The device modifications described in this notification do not affect the technological characteristics for the Micro-Infusion System.

Test Summary
Electrical safety and system testing confirmed the PT-2B operates as intended with the Micro-Infusion Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2006

EKOS Corporation
% Ms. Jocelyn Kersten
Vice President, Regulatory
and Clinical Affairs
11911 Northcreek Parkway South
Bothell, Washington 98011

Re: K062508
Trade Name: Micro-Infusion System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: NUI
Dated: November 2, 2006
Received: November 6, 2006

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 as a box warning, immediately following the indications for use, in the device's labeling:

"The safety and effectiveness of the EKOS Micro-Infusion System for thrombolytic therapy in the neurovasculature have not been established. Further clinical studies are necessary to ensure that use of devices to deliver thrombolytic therapy into the neurovasculature does not result in an increased incidence of adverse events (e.g., intracranial hemorrhage)."

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) 276-0115. 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.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062508

Device Name: Micro-Infusion System

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

The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro-Infusion System may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/5/06