

JAN 6 2006

## Section 4. 510(k) Summary

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| <b>General Provisions</b> | Submitter's Name and Address | EKOS Corporation<br>22030 20 <sup>th</sup> Ave. SE<br>Suite 101<br>Bothell, WA 98021 |
|                           | Contact Person               | Jocelyn Kersten<br>425-482-1108<br>425-482-1109 (fax)<br>jkersten@EKOSCORP.com       |
|                           | Classification Name          | Ultrasound, Infusion, System (NUI)   |
|                           | Common or Usual Name         | Ultrasound Infusion Catheter   |
|                           | Proprietary Name             | EKOS Micro- Infusion System  |

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| <b>Name of Predicate Device</b> | <u>Predicate Device</u>  | <u>510(k) Reference Nos.</u> |
|                                 | EKOS Peripheral Infusion System<br>EKOS Micro- Infusion System | K050563<br>K051225           |

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| <b>Device Description</b> | 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. |
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| <b>Intended Use</b> | <p>The EKOS Micro- Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.</p> <p>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.</p> |
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| <b>Summary of Technological Characteristics</b> | The proposed EKOS Micro- Infusion Catheter is similar in construction and materials to the EKOS Micro-Infusion Catheter previously cleared under K051225 and K050563. |
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| <b>Test Summary</b> | The proposed EKOS Micro- Infusion System is considered to be substantially equivalent to the currently marketed EKOS Micro- Infusion System based on a comparison of the intended uses and designs and results of the testing and evaluations performed. |
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JAN - 6 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jocelyn Kersten  
Director, Regulatory Affairs  
EKOS Corporation  
22030 20<sup>th</sup> Avenue SE, Suite 101  
Bothell, Washington 98021

Re: K053437  
Trade Name: EKOS Micro-Infusion Catheter  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic intravascular catheter  
Regulatory Class: II  
Product Code: NUI  
Dated: December 6, 2005  
Received: December 9, 2005

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 (301) 443-6597 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): K053437

Device Name: EKOS 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.

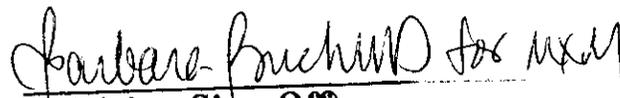
Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(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)

  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

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