FEB 18 2004

K040139

Appendix E
510(k) Summary of Safety and Effectiveness

Submitted by	Kirk Seward Vice President and Chief Technology Officer EndoBionics, Inc. 3077 Teagarden Street San Leandro, CA 94577 Telephone: 510 614-4550 Facsimile: 510 667-0435
Contact Person	Same as above
Date Summary Prepared	February 9, 2004
Trade Name	EndoBionics MicroSyringe (μSyringe) Infusion Catheter
Common Name	Continuous Flush Infusion Catheter (per 21 CFR 870.1210)
Performance Standards	Not promulgated for Continuous Flush Infusion Catheters
PROCODE/Classification	KRA/Class II
Panel	Cardiovascular

Predicate Devices

Dispatch Coronary Infusion Catheter K932616
Manufactured by SCIMED Life Systems, Inc.

Selective Infusion II Catheter K914751
Manufactured by ACS/Guidant, Inc.

Isolate Infusion Catheter System K913517
Manufactured by Lake Region, Inc.

Device Description

The EndoBionics μSyringe is a wire-guided endovascular catheter that consists of a perpendicular microneedle delivery port, which is sheathed by and contained within a semi-rigid polymer balloon actuator. The device is advanced over a 0.014" guidewire, using a single operator method, into the treatment vessel and hydraulically actuated to move the needle delivery port into the vessel in order to deliver substances to 2.5 mm vascular structures.

Intended Use

In selective areas of 2.5 mm diameter peripheral and coronary vessels, the μSyringe Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents that are indicated for delivery into the vessel wall or perivascular area. The μSyringe Infusion Catheter is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

Technological Characteristics
All materials used in the manufacture of the μSyringe are suitable for this use and have been used in several previously cleared products.

Testing
The following testing was conducted to ensure the μSyringe met all specifications:

- Balloon Minimum Burst Strength
- Balloon Compliance (Distensibility)
- Balloon Inflation/Deflation Performance
- Balloon Fatigue
- Bond Strengths
- Catheter Diameter and Balloon Profile
- Tip Pull Test
- Over-the-Arch Torque Strength Test
- Over-the-Arch Torque Response Test
- Balloon Preparation
- Catheter Body Burst Pressure
- Biocompatibility Testing
- In-vivo Safety

The results of the above tests demonstrated that the device is as safe and effective as the legally marketed predicate devices. All components, subassemblies and/or full devices met the required specifications for the above tests. Additional tests were performed to determine performance of the μSyringe in fluid delivery and integrity of device components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

EndoBionics, Inc.
c/o KEMA Quality B.V.
Ms. Patricia L. Murphy
4377 County Line Road
Chalfont, PA 18914

Re: K040139
Trade/Device Name: EndoBionics MicroSyringe (μSyringe) Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 20, 2004
Received: January 22, 2004

Dear Ms. Murphy:

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,

Donna R. Lochner

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

Enclosure

K040139

Appendix J
Indications for Use Form

Indications for Use

510(k) Number (if known): K040139

Device Name: EndoBionics MicroSyringe (µSyringe) Infusion Catheter

Indications For Use:

In selective areas of 2.5 mm diameter peripheral and coronary vessels, the µSyringe Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents that are indicated for delivery into the vessel wall or perivascular area. The µSyringe Infusion Catheter is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

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)

Donna R Bochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040139