DEC 17 2004

1100 East Hector Street, Suite 245, Conshohocken, PA 19428

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K042399

1. **Submitter's Identification:**

   Rex Medical, LP
   1100 East Hector Street, Suite 245
   Conshohocken, PA 19428

   Date Summary Prepared: August 27, 2004

   Contact:

   Denise Flamer
   Development Engineer

2. **Name of the Device:**

   Short Introducer Sheath

3. **Predicate Device Information:**

   K#032569, Rex Medical Short Introducer Sheath

4. Device Description:

The Rex Medical Short Introducer Sheath, offered in both 6F and 7F sizes, is a vascular access device consisting of a central lumen, angled side arm extension, and a hemostasis valve. The device is used under identical indications for use as the predicate device, as well other substantially equivalent 510(K) cleared devices.

5. Intended Use:

The Short Introducer Sheath is used to facilitate placing a catheter through the skin into a graft. The dilator is an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling system.

6. Comparison to Predicate Device:

Both the Short Introducer Sheath and the modified Short Introducer Sheath are provided in 6F and 7F sizes. Both consist of a radio-opaque distal tip which allows the physician to visually identify the position of the distal tip when located in the graft. A 45° sidearm located on the sheath hub incorporates an extension tube, female luer, and tubing clamp which allow for infusion or aspiration through the sheath as required during a procedure. An integrated hemostasis valve prevents blood loss or air introduction during use. The sheath is packaged with a dilator which allows for easy insertion over a guidewire. The dilator snaps into the sheath hub to increase the ease of insertion into a dialysis graft. The changes to the device are materials used in the device and improve the efficiency of the manufacturing process.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

All testing performed on the Short Introducer Sheath was derived from the risk assessment which evaluated the effects of the changed materials from the original Short Introducer Sheath. Test methodology and acceptance criteria were derived from ISO 11070, Sterile Single-Use Intravascular Catheter Introducers. All materials used in the Short Introducer Sheath were tested according to ISO 10993, Biological Evaluation of Medical Devices.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The subject device, Short Introducer Sheath, has identical indications for use as the original Rex Medical Short Introducer Sheath. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the Short Introducer Sheath is substantially equivalent to the original Rex Medical Short Introducer Sheath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Rex Medical
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K042399
Short Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: November 29, 2004
Received: December 3, 2004

Dear Ms. Goldstein-Falk:

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) 594-4646. 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

Indications for Use

510(k) Number (if known): K042399

Device Name: Rex Medical Short Introducer Sheath

Indications For Use:

The Short Introducer Sheath is used to facilitate placing a catheter through the skin into a graft. The dilator is an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling system.

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. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042399