REX MEDICAL

AUG 2 2 2007

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 l990 and 21 CFR §807.92.

The assigned 510(k) number is: K071422

1. **Submitter's Identification:**

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

   Contact: Mr. Walter H. Peters
   Quality Manager

   Date Summary Prepared: April 30, 2007

2. **Name of the Device:**

   Hemo-Stream™ True Over the Wire Dialysis Catheter

3. **Predicate Device Information:**

   1) K023847, Hemo-Stream™ Hemodialysis Catheter Set
   2) K040736, Vaxcel Plus Dialysis Catheter
   3) K012365, Vaxcel Dialysis Catheter

4. **Device Description:**

   The Rex Medical Hemo-Stream™ True Over the Wire Dialysis Catheter is a chronic hemodialysis catheter that can achieve high flow rates at low arterial pressures.

   The Hemo-Stream™ True Over the Wire Dialysis Catheter will be available in lengths of 24, 28, 32, 36 and 40cm.

   The device is used in exactly the same manner as the predicate devices and other substantially equivalent 510(k) cleared devices.

5. **Intended Use:**

   The Hemo-Stream™ True Over the Wire Dialysis Catheter is designed for chronic hemodialysis and apheresis.

6. **Comparison to Predicate Devices:**
   See next page

ATTACHMENT #2

Special 510(k): Device Modification
Hemo-Stream Hemodialysis Catheter

Attribute	Rex Medical Hemo-Stream™ True Over the Wire Dialysis Catheter (Subject Device)	Rex Medical Hemo-Stream™ Hemodialysis Catheter Set (K023847 - Predicate)	Vaxcel Plus Hemodialysis Catheter Set (K040736 - Predicate)	Vaxcel Hemodialysis Catheter Set (K012365 - Predicate)
Catheter Type	Implanted Vascular Access	Implanted Vascular Access	Implanted Vascular Access	Implanted Vascular Access
Intended Use	Hemodialysis and Apheresis	Hemodialysis and Apheresis	Hemodialysis and Apheresis	Hemodialysis and Apheresis
Lumen Configuration	3 Kidney Shaped Arterial Lumens, 1 Round Venous Lumen	4 Oval Arterial Lumens 1 Square Venous Lumen	1 "D" Arterial Lumen 1 "D" Venous Lumen	1 "D" Arterial Lumen 1 "D" Venous Lumen
Catheter O.D.	15.5F	16F	16F Proximal/14.5F Distal	16F Proximal; 14F Distal
Arterial/Venous Access Lumens	Yes	Yes	Yes	Yes
Color Coded Female Luers	Red: Arterial, Blue: Venous	Red: Arterial, Blue: Venous	No	Red: Arterial; Blue: Venous
Color Coded Clamp on Extensions	No	Red: Arterial, Blue: Venous	Red: Arterial, Blue: Venous	Red: Arterial; Blue: Venous
Rotating Suture Wing on Cath. Hub	No	Yes	Yes	Yes
Catheter Cuff for Tissue In-Growth	Yes	Yes	Yes	Yes
Radiopaque Catheter Lumen	20% Barium Sulfate	20% Barium Sulfate	Radiopaque, unknown loading	Radiopaque, unknown loading
Offset Tip for Arterial / Venous Separation	1.125" Separation	1" Separation	0.675" Separation	0.675" Separation
Hub junction for catheter lumen / extension tubing	Injection Molded, One Piece Hub	Integrated clamshell hub covering sealed junctions	Insert Molded hub to form connection of extension tubing to lumens	Insert Molded hub to form connection of extension tubing to lumens
Dilator Provided for Catheter Insertion	16F Rex Dilator	18F Cook Coons Dilator	15F Tear-Away Introducer Sheath	14F Tear-Away Introducer Sheath
Tunneling Tool provided for Catheter Insertion	Tunneling Tool w/integrated Handle	Tunneling Tool w/integrated Handle	Trocar device with barbs to attach to the catheter tip	Trocar device with barbs to attach to the catheter tip
Injection Sites supplied with Catheter	Qty. 2: Latex Free Injection Sites Provided	Qty. 2: Latex Free Injection Sites Provided	Qty: 2: Injection Sites (material composition not known)	Qty: 2: Injection Sites (material composition not known)
Priming Volume Printed on Female Luers	No	Yes	Yes	Yes
Catheter Identification and Reference size printed on Catheter Hub	Yes	Yes	Yes	No

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

Comparative functional testing to the predicated devices was performed based on ISO 10555-1 and the FDA's Reviewer Guidance for Long Term and Short Term Intravascular Catheters. Material testing also included ISO 10993 Biocompatibility Testing. Testing results revealed the subject device to be substantially equivalent to the predicate devices.

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

Not applicable as there are no new indications for use which must be supported by clinical data.

9. **Conclusions:**

The subject device, the Hemo-Stream™ True Over the Wire Dialysis Catheter, has the same intended use as the predicate devices, Hemo-Stream™ Hemodialysis Catheter Set (K023847), the Vaxcel Plus Dialysis Catheter (K040736) and the Vaxcel Dialysis Catheter (K012365). Bench testing and non-clinical testing supplied within our submission demonstrates that there are not any differences in their technological characteristics thereby not raising any new questions of safety and effectiveness. Therefore, the Hemo-Stream™ True Over the Wire Dialysis Catheter is substantially equivalent to the predicate devices, the Hemo-Stream™ Hemodialysis Catheter Set (K023847), the Vaxcel Plus Dialysis Catheter (K040736) and the Vaxcel Dialysis Catheter (K012365).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rex Medical, LP
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd.
Suite 200
GREAT NECK NY 11021

AUG 2 2 2007

Re: K071422
Trade/Device Name: Hemo-Stream™ True Over the Wire Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: August 3, 2007
Received: August 10, 2007

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, 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,

for NCB

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ATTACHMENT #2

Exhibit B

Indications For Use

510(k) Number (if known): K071422

Device Name: Hemo-Stream™ True Over the Wire Dialysis Catheter

Indications For Use:

The Hemo-Stream™ True Over the Wire Dialysis Catheter is designed for chronic hemodialysis and apheresis.

Prescription Use __X____ **OR** **Over-The Counter Use**_____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

(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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K071422