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

510(K) SUMMARY

NOV 18 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: K102043

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: July 6, 2010

2. **Name of the Device:**

   UltraStream Chronic Hemodialysis Catheter

3. **Predicate Device Information:**

   1) K071422, Hemo-Stream™ True Over the Wire Dialysis Catheter

4. **Device Description:**

   The Rex Medical UltraStream Chronic Hemodialysis Catheter is a chronic hemodialysis catheter that can achieve high flow rates at low arterial pressures.

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

5. **Intended Use:**

   The UltraStream Chronic Hemodialysis Catheter Set is designed for chronic hemodialysis and apheresis.

6. **Comparison to Predicate Devices:**

   See next page

Attribute	Rex Medical UltraStream Chronic Hemodialysis Catheter (Subject Device)	Rex Medical Hemo-Stream™ True Over the Wire Dialysis Catheter (K071422 - Predicate)
Catheter Type	Implanted Vascular Access	Implanted Vascular Access
Intended Use	Hemodialysis and Apheresis	Hemodialysis and Apheresis
Lumen Configuration	2 Kidney Shaped Arterial Lumens, 1 Round Venous Lumen	3 Kidney Shaped Arterial Lumens, 1 Round Venous Lumen
Catheter O.D.	15.5F	15.5F
Arterial/Venous Access Lumens	Yes	Yes
Color Coded Female Luers	Red: Arterial, Blue: Venous	Red: Arterial, Blue: Venous
Color Coded Clamp on Extensions	No	No
Rotating Suture Wing on Cath. Hub	No	No
Catheter Cuff for Tissue In-Growth	Yes	Yes
Radiopaque Catheter Lumen	20% Barium Sulfate	20% Barium Sulfate
Offset Tip for Arterial / Venous Separation	1.125" Separation	1.125" Separation
Hub junction for catheter lumen / extension tubing	Injection Molded, One Piece Hub	Injection Molded, One Piece Hub
Dilator Provided for Catheter Insertion	16F Rex Dilator	16F Rex Dilator
Tunneling Tool provided for Catheter Insertion	Tunneling Tool	Tunneling Tool
Injection Sites supplied with Catheter	Qty. 2: Latex Free Injection Sites Provided	Qty. 2: Latex Free Injection Sites Provided
Priming Volume Printed on Female Luers	No	No
Catheter Identification and Reference size printed on Catheter Hub	No	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 device.

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 UltraStream Chronic Hemodialysis Catheter, has the same intended use as the predicate device, the 15.5F Hemo-Stream™ True Over the Wire Hemodialysis Catheter (K071422). 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 UltraStream Chronic Hemodialysis Catheter is substantially equivalent to the predicate device, the Hemo-Stream™ True Over the Wire Hemodialysis Catheter (K071422).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV 18 2010

Re: K102043
Trade/Device Name: UltraStream Chronic Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: October 25, 2010
Received: October 26, 2010

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 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 and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, MD, Director (Acting)
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

NOV 1 8 2010

Indications For Use

510(k) Number (if known): K102043

Device Name: UltraStream Chronic Hemodialysis Catheter

Indications For Use:

The UltraStream Chronic Hemodialysis Catheter is designed for chronic hemodialysis and apheresis.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(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, Gastro-Renal, and Urological Devices
510(k) Number K102043