DEC 1 6 2003

Attachment 1

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: K033793

1. **Submitter's Identification:**

Rex Medical
555 North Lane
Suite 6101
Conshohocken, PA 19428
(610) 940-0665

Contact: Mr. Michael Paris

Date Summary Prepared:

October 29, 2003

2. **Name of the Device:**

Rex Medical Cleaner II Rotational Thrombectomy System".

3. **Common or Usual Name:**

Intraluminal Artery Stripper (Peripheral Atherectomy Catheter)

4. **Predicate Device Information:**

1) K031610: Cleaner™ Rotational Thrombectomy System
2) K902327: Embolectomy Catheter
3) K032393: Stopcock
4) K022170: Inner-Lock™ Sheath Introducer
5) K032569: Short Sheath Introducer

5. **Device Description:**

The Rex Medical Cleaner II Rotational Thrombectomy System is a battery operated, hand held, wall contacting, rotational thrombectomy device which provides an effective means to restore patency to occluded synthetic dialysis grafts. The rotational wire, with integrated soft distal tip, provides an atraumatic approach to mechanical thrombectomy. The Cleaner II macerates clot into particulate size that is not harmful to the patient. The integrated Embolectomy balloon provides a means to remove macerated thrombi, as well as wall adherent thrombi, from the dialysis graft. If required, the Embolectomy balloon located on the Cleaner II device may be used to remove any additional thrombi or emboli from the patient after the initial thrombectomy procedure has been performed.

6. **Intended Use:**

The Rex Medical Cleaner II Rotational Thrombectomy System permits mechanical declotting and removal of thrombi and emboli in synthetic dialysis grafts. The Embolectomy balloon component, located on the Cleaner II Device, may be used for subsequent Embolectomy procedures to remove emboli and thrombi in the arterial system communicating with the synthetic dialysis graft

7. **Comparison to Predicate Devices:**

The Cleaner II device has the same technological features as the predicate devices.

The following testing was performed to prove substantial equivalence of the Rex Medical Cleaner II Rotational Thrombectomy Device to the predicate devices:

Stall Torque Test
Tensile Test
Valve Compression Test
Contrast Infusion Test
Wire Fatigue Test
Clot Maceration in Graft
Dimensional Analysis of Balloon Catheter
Balloon Leakage and Damage (Per ISO 10555-4)

Testing proved that the Rex Medical Cleaner II device is as safe and effective as the predicate devices.

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Performance testing, which includes testing protocols, testing results and conclusions, were based on ISO 10555-1, ISO 10555-4, and FDA's "Guidance on Pre-market Notification (510(k)) Submission for Short-Term and Long-Term Intravascular Catheters", was submitted with this submission.

Statistical sampling rationale for choosing the number of devices that were tested was based on ISO 2859-1 sampling plans in accordance with our projected lots (batch) size.

Testing results revealed that the Rex Medical Cleaner II Rotational Thrombectomy System device is substantially equivalent to the predicate devices.

9. **Conclusions:**

The subject device, Rex Medical Cleaner II Rotational Thrombectomy System, has the same intended use as the predicate devices. Moreover, bench testing contained in our submission and the non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, the Rex Medical Cleaner II Rotational Thrombectomy System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2003

Rex Medical Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K033793
Cleaner II Rotational Thrombectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Peripheral Atherectomy Catheter
Regulatory Class: Class II
Product Code: MCW
Dated: December 4, 2003
Received: December 5, 2003

Dear Mr. Mosenkis:

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) 594-4692. 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,

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

Enclosure

Exhibit B

510(k) Number (if known): K033793

Device Name: **Rex Medical Cleaner II Rotational Thrombectomy System**

Indications For Use:

The Rex Medical Cleaner II Rotational Thrombectomy System permits mechanical declotting and removal of thrombi and emboli in synthetic dialysis grafts. The Embolectomy balloon component, located on the Cleaner II Device, may be used for subsequent Embolectomy procedures to remove emboli and thrombi in the arterial system communicating with the synthetic dialysis graft

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K033793 (SM. K)