MAY 27 2003

K031610

Exhibit #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:_____

1. **Submitter's Identification:**

Rex Medical
555 North Lane
Suite 6101
Conshohocken, PA 19428

Contact: Mr. Michael Paris

Date Summary Prepared:

April 14, 2003

2. **Name of the Device:**

Rex Medical Cleaner™ Rotational Thrombectomy System".

3. **Predicate Device Information:**

1. K#990829, Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device, Arrow International, Inc., Reading, PA K#970080, Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device, Arrow International, Inc., Reading, PA

2. K#003570, Solera™ Bacchus™ Thrombectomy Catheter (BTC), Bacchus Vascular, Inc. Santa Clara, CA

4. **Device Description:**

The Rex Medical Cleaner™ 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™ macerates clot into particulate size that is not harmful to the patient.

5. **Intended Use:**

The Rex Medical Cleaner™ Rotational Thrombectomy System device permits mechanical declotting in synthetic dialysis grafts.

6. Comparison to Predicate Devices:

Attribute	Rex Medical Cleaner™ Rotational Thrombectomy System (Subject Device)	Arrow PTD (Predicate Device)
Catheter Type	Mechanical Thrombectomy Catheter	Mechanical Thrombectomy Catheter
Intended Use	Maceration of Clot	Maceration of Clot
Catheter Outer Diameter	6F Sheath Compatible	6F Sheath Compatible
Catheter Length	65cm	65cm
Drive Wire Diameter	.035"	0.041"
Cleaning Device Wire	.035" Guidewire	Nitinol Basket (0.015" X 4 Wires)
Distal Catheter Tip Configuration	Radiopaque Tip	Radiopaque Tip
Distal Wire Tip Configuration	Atraumatic Radiopaque Soft Distal Tip	Atraumatic Radiopaque Soft Distal Tip
Cleaning Device	Sinusoidal Wave formed in Drive Wire	Wire Basket Added to End of Drive Wire
Activation Switch	Push Button Switch Located on Handle	Push Button Switch Located on Handle
Means to Protect Distal Wire Segment	Slide Mechanism on Handle to Slide Catheter Over Cleaning Device	Slide Mechanism on Handle to Slide Catheter Over Cleaning Device
Side-Port Extension w/Female Luer	Located on Handle	Locate on Handle
Ergonomic Handle	Yes	Yes
Packaging	Tray w/Tyvek Lid	Tray w/Tyvek Lid
Energy Transmitted to Graft from Device (6mm Id Graft)	22.6J	31.1J

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

Performance testing, which includes testing protocols, testing results and conclusions, based on ISO 10555-1, 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™ Rotational Thrombectomy System device is substantially equivalent to the predicate device.

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

In-Vivo (animal) test studies have proven that the Cleaner™ Rotational Thrombectomy device will macerate clot formation in synthetic dialysis grafts as effectively, efficiently, and as safely as the predicate device.

9. **Conclusions:**

The subject device, Rex Medical Cleaner™ Rotational Thrombectomy System. has the same intended use as the predicate devices, the Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device, and the Solera™ Bacchus™Thrombectomy Catheter (BTC). 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™ 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

MAY 27 2003

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

Re: K031610
Cleaner™ Rotational Thrombectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Catheter, Peripheral, Atherectomy
Regulatory Class: Class II (two)
Product Code: MCW
Dated: May 21, 2003
Received: May 22, 2003

Dear Ms. Goldstein-Falk:

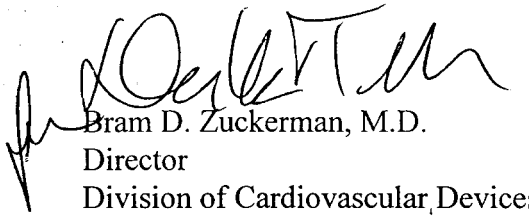
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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,



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): K031610

Device Name: Rex Medical Cleaner™ Rotational Thrombectomy System

Indications For Use:

The Rex Medical Cleaner™ Rotational Thrombectomy System device permits mechanical declotting in synthetic dialysis grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031610