JAN 2 1 2003

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K022170

1. **Submitter's Identification:**

Rex Medical
585 County Line Road
Radnor, PA 19087

Contact: Mr. Paul Tashjian

Date Summary Prepared:

July 1, 2002

2. **Name of the Device:**

Inner-Lock Locking Introducer Sheaths

3. **Predicate Device Information:**

K#954234, K#984260: PINNACLE™ R/O or RADIFOCUS® Introducer R/O device, Terumo Medical Corporation, Elkton, MD

4. **Device Description:**

The Rex Medical, Inner-Lock Locking Introducer Sheaths, 6F and 7F is a vascular access device consisting of a central lumen, an angled side arm extension and a hemostasis valve. The distal tip contains a retention mechanism that is operated via a control arm on the proximal hub. The device is used in exactly the same manner as the predicate device and other substantially equivalent 510(k) cleared devices.

5. **Intended Use:**

The Inner-Lock Locking Introducer Sheaths are used to facilitate placing a catheter through the skin into a graft. The Inner-Lock 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 sheath.

K022170

6. **Comparison to Predicate Devices:**

Discussion of Similarities

The Inner-Lock Locking Introducer Sheaths are similar to the Terumo RADIFOCUS ® Introducer R/O device, in that both devices make use of a tapered distal tip with a central lumen to pass over a guidewire and dilator combination; both devices have an elastomer valve, side port and a radio opaque indicator and proximal hubs and extensions are similar in function and material characteristics. Both devices can be used for dialysis graft access.

Discussion of Differences

The Inner-Lock Locking Introducer Sheaths are different from the Terumo RADIFOCUS ® Introducer R/O device, by means of an angled side port and a device retention feature. The angled sidearm may reduce shear force during fluid movement. The retention feature may reduce the risk of the device accidentally being dislodged from the patient. The retention mechanism provides an alternative to suturing the device hub to the skin.

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

Comparative functional testing (to the predicate) was performed based on ISO 10555-1, ISO 11070 and FDA's Reviewer Guidance for Short-Term and Long-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, Inner-Lock Locking Introducer Sheaths, have the same intended use and characteristics as the predicate device, the Terumo RADIFOCUS® Introducer R/O device. Moreover, bench testing contained in our submission and 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 Inner-Lock Locking Introducer

K022170

Sheaths are substantially equivalent to the predicate device, the Terumo RADIFOCUS® Introducer R/O device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2003

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

Re: K022170
Rex Medical Inner-Lock Locking Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 24, 2002
Received: October 28, 2002

Dear Ms. Goldstein-Falk:

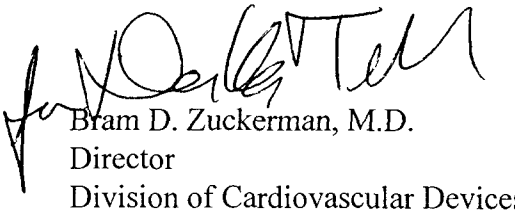
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

Also, please 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. 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): K022170

Device Name: Inner-Lock Locking Introducer Sheaths

Indications For Use:

The Inner-Lock Locking Introducer Sheaths are used to facilitate placing a catheter through the skin into a graft. The Inner-Lock 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 sheath.

(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 Cardiovascular Devices

510(k) Number K022170

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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