JUL 2 2 2004

3. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: ~~TBD~~ K041151

Applicant Information:

Date Prepared:	April 28, 2004
Name:	Kerberos Proximal Solutions, Inc.
Address:	1400 Terra Bella, Suite E Mountain View, CA 94043 650-254-1005 Ext 313
Contact Person:	Michael A. Daniel
Phone Number:	Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number:	925-254-5187

Device Information:

Classification:	Class II Percutaneous Catheter / Vascular Clamp
Trade Name:	Kerberos Occluding Guide Catheter and Accessories
Common Name:	Percutaneous Catheter / Temporary Intravascular Occluding Catheter
Classification Name:	Catheter, Percutaneous 74 DQY /21 CFR 870.1250 Catheter, Intravascular Occluding, Temporary 74 MJN /21 CFR 870.4450

Predicate Devices:

The Kerberos Proximal Solutions Occluding Guide Catheter (OGC) and Accessories is substantially equivalent in intended use and method of operation to a combination of the following predicate devices:

1) K021899 – Concentric Medical, Inc.; Balloon Guide Catheter
2) K002286 – Cook Inc.; LDOB Occlusion Balloon Catheter
3) K033441 – Boston Scientific Corporation; 6F RunWay Guide Catheter
4) K984214 – Cordis; Commodore Temporary Occlusion Balloon Catheter
5) K973298 – Cardima; Vueport Balloon OGC

Device Description:

The Kerberos Proximal Solutions Occluding Guide Catheter (OGC) is a sterile single-use percutaneous catheter consisting of a dual lumen variable stiffness braided shaft catheter incorporating a flush mounted balloon at the distal tip. Guidance and tracking of the catheter through the coronary, neuro or peripheral vasculature is accomplished by torquing of the catheter and/or the use of a guide wire.

Intended Use:

The Kerberos Proximal Solutions Occluding Guide Catheter and Accessories are intended to facilitate the use and guidance of intravascular catheters into selected blood vessels in the peripheral, cardiovascular and neurovascular systems. The balloon provides temporary vascular occlusion during these percutaneous procedures.

Comparison to Predicate Device(s):

The Kerberos Proximal Solutions Occluding Guide Catheter and Accessories are substantially equivalent to a combination of the following devices in terms of indications for use, embodiment, shape, appearance and function:

1) K021899 – Concentric Medical, Inc.; Balloon Guide Catheter
2) K002286 – Cook Inc.; LDOB Occlusion Balloon Catheter
3) K033441 – Boston Scientific Corporation; 6F RunWay Guide Catheter
4) K984214 – Cordis; Commodore Temporary Occlusion Balloon Catheter
5) K973298 – Cardima; Vueport Balloon OGC

***In Vitro*, *In Situ* and *In Vivo* Test Data:**

Design analysis, *in vitro* and *in vivo* data confirm that basic functional characteristics are substantially equivalent to the predicate device cited. Routine device evaluation consists of testing specified in FDA's "Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Laser, Intravascular Stents" and included *in vitro* dimensional analysis, balloon performance, torque and kink resistance, leakage, bond strengths and biocompatibility tests. All data fell well within internal specification requirements, as well as external standard requirements and predicate performance expectations.

Summary:

Based upon the product technical information, intended use, performance, sterilization and biocompatibility information provided in this pre-market notification, the Kerberos Proximal Solutions Occluding Guide Catheter has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Kerberos Proximal Solutions
c/o Mr. Tom Mason
1400 Terra Bella Avenue, Suite K
Mountain View, CA 94043

Re: K041151
Kerberos Occluding Guide Catheter and Accessories
Regulation Number: 21 CFR 870.1250
Regulation Name: Occluding Guide Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 28, 2004
Received: May 3, 2004

Dear Mr. Mason:

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,

Donna R. Vochmer

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

Enclosure

K041151

Indications for Use

510(k) Number (if known): ~~TBD~~ K041151

Device Name: **Kerberos Proximal Solutions Occluding Guide Catheter and Accessories**

Indications For Use:

The Kerberos Proximal Solutions Occluding Guide Catheter (OCG) and Accessories are intended to facilitate the use and guidance of intravascular catheters into selected blood vessels in the peripheral, cardiovascular and neurovascular systems. The balloon provides temporary vascular occlusion during these percutaneous procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vo-Linez

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041151