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GUARDDOG™ OCCLUSION SYSTEM
510(K) SUMMARY

SUBMITTER'S INFORMATION	Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433 Tel: (612) 780-4555 Fax: (612) 780-2227
CONTACT	Mark D. Stenoien Manager, Regulatory & Clinical Affairs
SUMMARY DATE	29 April 2003
DEVICE TRADE NAME	GuardDOG™ Occlusion System GuardDOG Occlusion Guide Wire, 300 cm GuardDOG Occlusion Guide Wire, 200 cm GuardDOG Inflation Device
COMMON NAME	Temporary Occlusion Catheter
DEVICE CLASS	Catheter, Intravascular Occluding, Temporary (MJN, 21 CFR 870.4450) Class II
LEGALLY MARKETED PREDICATE DEVICES	PercuSurge Temporary Occlusion Balloon System - K972777 Medtronic PercuSurge Inc. 540 Oakmead Parkway Sunnyvale, CA 94086 Equinox Occlusion Balloon – K990487 Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618

DEVICE DESCRIPTION

The GuardDOG System consists of two components: a carbon dioxide (CO2) Inflation Device and a balloon Occlusion Guide Wire. The GuardDOG Inflation Device is a disposable syringe assembly, which is prepackaged with carbon dioxide and is used to inflate the Occlusion Guide Wire. The GuardDOG Occlusion Guide Wire is a 200 or 300cm long by 0.014" outside diameter Catheter with an inflatable balloon on the distal end. The guide wire is inflated via a detachable hub, which is connected to the Inflation Device.

INTENDED USE

The GuardDOG™ Occlusion System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion.

The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature.

COMPARISON TO PREDICATE DEVICE:

Table 1 summarizes key technical characteristics and physical properties of the Perma-Pass Graft and the predicate device. This information is provided for two graft sizes denoted as follows: thin wall 6mm internal diameter (6T), and standard wall 6mm internal diameter (6S).

Comparison Table: Technical Features			
	GuardDOG™ Occlusion System	PercuSurge™ GuardWire Temporary Occlusion Balloon System – K972777	MicroTherapeutics, Inc. Equinox™ Occlusion Balloon – K990487
Indication / Intended Use	The GuardDOG Occlusion System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion. The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature.	The PercuSurge Temporary Occlusion Balloon System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion. The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature.	The MicroTherapeutics, Inc. Occlusion Balloon Catheter is designed for use in blood vessels where temporary occlusion is desired. The MTI Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow.
Major Components	GuardDOG Occlusion Guide Wire, GuardDOG Inflation Device	GuardWire Temporary Occlusion Catheter, MicroSeal® Adapter, (optional: Export® Catheter)	Equinox Occlusion Balloon Catheter, SilverSpeed 0.010" Guidewire, and a rotating hemostatic valve
Accessories Included	Scissors, introducer	Fixed volume syringe, introducer	
Balloon Catheter			
Number of lumens	Single lumen	Single lumen	Single lumen
Outer Diameter	0.014 inch	0.014 inch	2.8-2.2 French (0.037-0.029 inch)
Length	200 or 300 cm	175 cm	150 cm
Inflated balloon	3-6 mm	4, 4.5, and 5 mm	4 mm
Balloon Material	Compliant elastomer	Compliant elastomer	Compliant elastomer

Inflation Medium	CO2	1:1 solution of 60% contrast with saline	1:1 solution of 60% contrast with saline
Sterility	Sterile, intended for single use.	Sterile, intended for single use.	Sterile, intended for single use.
Biocompatibility	Biocompatible in accordance with ISO 10993-1 Biological Evaluation of Medical Devices for external communicating, blood contact of short duration device.		Biocompatible in accordance with ISO 10993-1 Biological Evaluation of Medical Devices for external communicating, blood contact of short duration device.

The GuardDOG Occlusion System is equivalent to the predicate devices in technical characteristics.

Functional and mechanical integrity testing has been performed. The results verify equivalency to the predicate devices and appropriate safety and efficacy of the GuardDOG Occlusion System for the intended use.

One difference is that the GuardDOG Occlusion System uses CO2 gas as the inflation medium; both predicate devices use a 1:1 mixture of 60% contrast in saline. However, CO2 is an accepted contrast agent for use in the peripheral vasculature. A literature search was done to evaluate the effects of CO2 in the circulatory system. The results demonstrate that CO2 doses of 5-250cc are safe in the peripheral vasculature. The design of the GuardDOG System limits the potential exposure to CO2 to 5 cc or less. In addition, the GuardDOG is packaged such that CO2 is maintained at high purity (greater than 95%) and thus potential balloon failure will expose the patient to CO2 rather than to air embolism. Finally, the rated burst diameter of the GuardDOG Occlusion Guide Wire balloon is 9.26 mm and provides an acceptable margin of error over the recommended 3-6 mm vessel occlusion range. These results, individually and taken together, demonstrate equivalency to the predicate devices and appropriate safety and efficacy of the GuardDOG Occlusion System for the intended use.

NON-CLINICAL TESTS

Biocompatibility of the GuardDOG system was evaluated in compliance with Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies, 21 CFR Part 58 and according to the recommendations in ISO 10993-1 *Biological Evaluation of Medical Devices – Part One.* The results, reported in the Biocompatibility tab, demonstrate that the GuardDOG materials and manufacturing methods are appropriate and safe for the intended use. In addition, the GuardDOG System is sterilized according to industry standard procedures and is packaged appropriately in packaging that maintains a sterile barrier and device integrity as reported in the Packaging and Sterilization tab.

A Vessel Safety Animal Study was performed to compared the incidence of acute vessel injury between the GuardDOG Occlusion System and the Equinox Occlusion Balloon Catheter in a canine model. The study concluded that the GuardDOG performed well with regard to vessel occlusion and does not cause any significant vessel injury compared

to the predicate device. These results demonstrate appropriate safety of the GuardDOG Occlusion System for the intended use and equivalence to the predicate device.

Additional animal studies were conducted to evaluate device integrity, track to a targeted vascular site and deliver an infusion catheter device the intended vascular territory. The GuardDOG Occlusion System is compatible with standard interventional devices such as introducers, guide catheters, and infusion catheters and is equivalent to the predicate devices based on acceptable results in these tests.

CONCLUSION

The data presented in this Premarket Notification establish that the GuardDOG Occlusion System is equivalent to the predicate devices and demonstrate appropriate safety and efficacy of the GuardDOG Occlusion System for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2004

Possis Medical, Inc.
c/o Mr. Mark D. Stenoien
Manager, Clinical and Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K031357
Trade Name: GuardDOG Occlusion System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: II (two)
Product Code: MJN
Dated: February 17, 2004
Received: February 18, 2004

Dear Mr. Stenoien:

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) 594-4659. 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. Lo Cicero

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

Enclosure

GuardDOG™ Occlusion System
Indication For Use Statement

April 2003

The GuardDOG™ Occlusion System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion.

The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature.

Prescription use ✓

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031357