K062220

Section 3 – 510k Summary Information

AUG 11 2006

Applicant:	Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433-8003 Tel: (612) 780-4555 Fax: (612) 780-2227 ERN: 2183460
Contact Person:	Mark D. Stenoien Director of Worldwide Regulatory Affairs P. 763.717.1092 Email: mark.stenoien@possis.com
Date Prepared:	31 July 2006
Trade Name:	GuardDOG® Occlusion System
Common Name of Device/ Classification and Code:	Vascular Clamp Product Code: MJN Class II/21 CFR 870.4450 Cardiovascular
Predicate Device:	The GuardDOG Occlusion System - K031357 Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433-8003
Device Description:	The GuardDOG System consists of two components: an Occlusion Guide Wire and a carbon dioxide (CO2) Inflation Device. The GuardDOG Inflation Device is used to inflate the occlusion balloon and seal the guide Wire once it is in position.
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.
Summary of Technological Characteristics:	Representative samples of the device underwent testing including but not limited to mechanical testing, biocompatibility, sterility, and animal testing.
Conclusion:	Possis Medical, Inc. considers the GuardDOG Occlusion System to be substantially equivalent to the predicate device listed above 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.

Section 4 – General Information

Applicant:	Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433-8003 Tel: (612) 780-4555 Fax: (612) 780-2227 Establishment Registration Number: 2183460
Contact Person:	Mark D. Stenoien Director of World Wide Regulatory Affairs P. 763.717.1092 Email: mark.stenoien@possis.com
Date Prepared:	31 July 2006
Contract Manufacture:	Synovis Interventional Solutions Inc. 475 Apollo Dr. Lino Lakes, MN 55104 ERN #3004594493
Sterilizer Contractor:	Guide Wire: STERIS Isomedix Services 380 90th Ave. NW, Coon Rapids, MN 55433 ERN#2183744 Inflation Device: STERIS Isomedix Services 7828 Nagle Avenue Morton Grove, IL 60053 ERN#1450253
Trade Name:	GuardDOG™ Occlusion System
Common Name of Device/Product Classification and Code:	Vascular Clamp Product Code: MJN Class II/21 CFR 870.4450 Cardiovascular
Predicate Device:	The GuardDOG Occlusion System - K031357 Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433-8003
Device Description:	The GuardDOG System consists of two components: an Occlusion Guide wire and a carbon dioxide (CO2) Inflation Device. The GuardDOG Guide wire is 0.035" in size; 300cm in length (260cm working length); is compatible with a 0.038, or larger, guide catheter; has a shapeable tip; a radiopaque marker proximal and distal to the inflatable balloon; and a crimp zone that can be sealed to maintain balloon inflation on the proximal end. The GuardDOG Inflation device is used to inflate the occlusion balloon and seal the guide wire once it is in position. The GuardDOG Inflation device is a disposable CO2 delivery device with two

	integrated syringes and a gauge. One syringe contains 20cc of CO2 and the second syringe is used to evacuate air from the Occlusion Guide Wire. The gauge is used to measure pressure of CO2 delivered. The GuardDOG Inflation device is packaged in Tyvek pouch for sterilization and then into a sealable can to maintain the CO2 environment.
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.
Summary of Technological Characteristics:	Representative samples of the device underwent bench testing, including but not limited to mechanical testing, biocompatibility, sterility to demonstrate safety and effectiveness and appropriate functional and performance characteristics. Animal testing was conducted to demonstrate performance characteristics only.
Conclusion:	Possis Medical, Inc. considers the GuardDOG Occlusion System to be substantially equivalent to the predicate device listed above 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. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Possis Medical, Inc.
c/o Mr. Mark Stenoien
Director of Worldwide Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K062220
GuardDog Occlusion System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: II (Two)
Product Code: MJN
Dated: July 31, 2006
Received: August 2, 2006

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

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

Enclosure

Section 2 – Indications For Use Statement

510(k) Number (if known): K 062220

Device Name: The GuardDOG® Occlusion System

Indications for 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.

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

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

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062220