

K081454  
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## Section 5 – 510k Summary Information

JUN 13 2008

**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:** Mike Burnside  
Sr. Regulatory Affairs Associate  
Phone: (763) 780-4555  
Fax: (763) 780-2227  
Email: [mike.burnside@possis.com](mailto:mike.burnside@possis.com)

**Date Prepared:** May 22, 2008

**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 - K062220  
Possis Medical, Inc.  
9055 Evergreen Boulevard N.W.  
Minneapolis, MN 55433-8003

**Device Description:** The GuardDOG System consists of two components: An Occlusion Guidewire and a carbon dioxide (CO<sub>2</sub>) Inflation Device. The GuardDOG Inflation Device is used to inflate the occlusion balloon and seal the guidewire 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. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 13 2008**

Possis Medical, Inc.  
c/o Mr. Mike Burnside  
Sr. Regulatory Affairs Associate  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433

Re: K081454  
Trade/Device Name: GuardDOG Occlusion System  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II (Two)  
Product Code: MJN  
Dated: May 22, 2008  
Received: May 23, 2008

Dear Mr. Burnside:

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

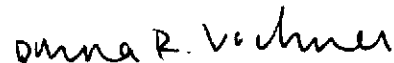
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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

Enclosure

**Indication for Use**

510(k) Number (if known): K 081454

Device Name: The GuardDOG<sup>®</sup> 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  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 OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Cochran  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K081454