510(k) Summary of Safety and Effectiveness

GEOMED
Medizin-Technik GmbH & Co. KG
Ludwigstaler Straße 27
D-78532 Tuttlingen / Germany

K102048

Titel: GEOMED Vascular Clamps

June 1, 2010

NOV - 9 2010

Submitter	GEOMED Medizin-Technik GmbH & Co. KG Ludwigstaler Strasse 27 D-78532 Tuttlingen Germany Thomas Haug President Telefon: ++49 7461 / 93 55 0 FAX: ++49 7461 / 93 55 93 E-mail: info@geomed.de
Application correspondent (consultant)	Harald Jung General Manager JUNG Consulting Unterer Winkel 3 D-78573 Wurmlingen Germany Telefon +49 7461-96 92 36 FAX +49 7461-96 92 37 E-mail: hjung@harald-jung.de
Trade Name	GEOMED Vascular Clamps
Common Name	Vascular Clamp
Product Code and Classification Name	DXC, Clamp, Vascular
Product Classification	21 CFR § 870.4450

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Predicate:

GEOMED Vascular Clamps are substantially equivalent to other legally marketed Vascular Clamps from different manufacturers, e.g. Aesculap Inc..

Device Description:

The GEOMED Vascular Clamps are reusable devices and provided non sterile. They must be thoroughly cleaned and sterilized before use.

GEOMED Vascular Clamps are made of Stainless Steel (following ASTM F 899-07). They are provided with ring handles and ratchet closures to adjust the amount of tension applied to the vessel for occlusion or partial occlusion.

The GEOMED Vascular Clamps are available in a wide variety of shapes, sizes and lengths to accomodate to the individual needs of the surgeon. Based on the anatomy of the site, the surgical technique chosen, the size and type of blood vessel and occlusion desired, the surgeon decides which clamp to use. During surgery the handles and shanks need to be out of the field of vision of the operative site and therefore a wide variety of instrument figures and sizes is necessary.

The Vascular Clamps occlude the arteries or veins with a tension that intends to produce minimal trauma to the vessels. They cover the vessel and stop the blood flow.

Indications for Use:

GEOMED Vascular Clamps are intended for use for temporary occlusion of blood vessels during surgical procedures.

Substantial Equivalence:

The GEOMED Vascular Clamps are substantial equivalent to the predicate device, since the basic features, design and intended uses are the same. The minor differences between the GEOMED Vascular Clamps and the predicate device have no effect on the performance, function or intended use of the device.

Design Verification Performance:

Tests for Cleaning and Sterilization are provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GEOMED Medizin-Technik GmbH & Co. KG
c/o Mr. Harald Jung
JUNG Consulting
Unterer Winkel 3
D-78573 Wurmlingen
Germany

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Re: K102048
Trade Name: Vascular Clamps
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: October 6, 2010
Received: October 8, 2010

Dear Mr. Jung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K102048

Device Name: **GEOMED Vascular Clamps**

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Indications for Use:

GEOMED Vascular Clamps are intended for use for temporary occlusion of blood vessels during surgical procedures.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102048