K100090

510(k) Summary Statement

FEB - 2 2010

Submitters Name: GENICON
6869 Sta Point Court
Suite #114
Winter Park, FL 32792
Ph: 1.321.297.1189
Fx: 1.407.679.0880

Contact Name: Melanie Murphy

Name of Device: Titanium Ligation Clip

Safety & Effectiveness Data Summary:

Classification Name: Clip, Implantable
Common/Usual Name: Ligation Clip
Proprietary Name: n/a at this time

Classification: Class II

Implantable Clip:	#79 FZP	Reg. #878.4300
Hemostatic Clip:	#79 MCH	Reg. #878.4300

Performance Standards: Devices are manufactured according to Good Manufacturing Practices (G.M.P.), Association for Advancement of Medical Instrumentation (A.A.M.I.) and American Society for Testing and Materials (A.S.T.M.) requirements and applicable Harmonized Standards ISO 13485.

Material Composition: A.S.T.M F-67 95, Grade I Titanium
I.S.O. #5832-2-93, Grade I Titanium

Intended Use: The GENICON implantable clips are intended for use during procedures for the purpose of approximating soft tissue, closing off vessels and other structures in order to stop bleeding or to connect internal tissues to aid in healing.

Device Description: The ligation clips are composed exclusively of titanium, and are supplied as sterile products in various sizes (mini-micro, micro, small, small-medium, medium, medium-large, large and extra large) with six clips per disposable holder. The titiaum used meets all requirements for A.S.T.M. specifications F-67 95 "Unalloyed Titanium for Surgical Implant Applications", Grade I and ISO 5832-2-93 and 10993 "Implants for Surgery – Metallic Materials – Part 2: Unalloyed Titanium".

Predicate Devices: Ethicon K830503

Comparison of Technological Characteristics: The titanium clip material and disposable holder material substantially equivalent to the predicate device. In function, the clips are the substantially equivalent to the predicate device as well.

Safety and Efficacy Information: Titanium is well recognized as being safe and effective for long term implantation. Millions of titanium clips are applied yearly and since inception in the 1960's attest to the wide acceptance of this method of hemostatic and ligation control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 2 2010

Genicon
% Mr. Gary W. Haberland
President
6869 Stapoint Court #114
Winter Park, Florida 32792

Re: K100090
Trade/Device Name: Genicon Ligation Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP, MCH
Dated: January 08, 2010
Received: January 12, 2010

Dear Mr. Haberland:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K100090

Section 4 - Indications for Use

Device Name: GENICON Ligation Clip

Indications for Use:

The GENICON implantable clips are intended for use during procedures for the purpose of approximating soft tissue, closing off vessels and other structures in order to stop bleeding or to connect internal tissues to aid in healing.

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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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