NOV - 8 2011

K111930

510(k) Summary

Date:	**28 October 2011**
Sponsor:	**Ackermann Instrumente GmbH** Eisenbahnstrasse 65-67 78604 Rietheim-Weilheim Germany Phone: +49 (0) 7461-966170 Fax: +49 (0) 7461-9661770
Contact Person:	Rolf Ackermann President
Proposed Trade Name:	Europclip®
Device Classification	Class II
Classification Name:	Implantable clip, Haemostatic clip
Regulation:	878.4300
Device Product Code:	FZP, MCH
Device Description:	The Europclip is a chevron-shaped clip having a heart-shaped cross-section and transverse grooves across the inner surface of the clip. The clips are supplied sterile, available in four sizes and pre-loaded in a disposable cartridge.
Intended Use:	The Europclip is indicated for use in surgical procedures on vessels or other tubular structures where a metal ligating clip is required. The device is intended to occlude the tubular structure by compression.
Materials:	The Europclip is manufactured from commercially pure titanium as described by ISO 5382-2.
Predicate Devices:	Nexus Ligating Clips (K053255) Miltex Ligating Clips (K052018) Titanium Ligation Clip (K100090)
Performance Data:	The Europclip functions in the same manner as the predicates to occlude blood vessles.
Technological Characteristics:	The Europclip possesses the same technological characteristics as one or of the predicate devices. These include: • intended use (as described above) • basic design (chevron-shaped with heart-shaped cross-section), • material (titanium), • sizes (dimensions are comparable to those offered by the predicate systems) and The fundamental scientific technology of the Europclip is the same as previously cleared devices. Therefore the Europclip can be found substantially equivalent to the predicate devices.

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

Ackerman Instrumente GmbH
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Karen E. Warden, PhD
8202 Sherman Road
Chesterland, Ohio 44026-2141

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Re: K111930
Trade/Device Name: Europclip®
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP, MCH
Dated: October 28, 2011
Received: October 31, 2011

Dear Dr. Warden:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111930

Device Name: Europclip®

Indications For Use:

The Europclip® is indicated for use in surgical procedures on vessels or other tubular structures where a metal ligating clip is required. The device is intended to occlude the tubular structure by compression.

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)

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

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