

K972745

**510(k) Summary / Statement**

OCT 21 1997

**Submitters Name:** EISNER USA  
15 Caswell Lane/Boat Yard Square  
Plymouth, MA 02360  
Ph: 508-747-6006 Fax: 508-747-5118

**Contact Name:** Ellen Henke-Knupp, Official Corespondent

**Name of Device:** Titanium Hemostatic Clip

**SAFETY & EFFECTIVENESS DATA SUMMARY**

Classification Name: Clip, Implantable  
Common/Usual Name: Titanium Hemostatic Clip  
Proprietary Name: N/A at this time

Classification: Class II  
Implantable Clip # 79 FZP Reg. # 878.4300

**Performance Standards:** Devices are manufactured according to cGMP's, AAMI and ASTM requirements, and applicable Harmonized Standards ISO 9002/ EN 46002.

**Material Composition:** ASTM F-67 95, Grade I Titanium.

**Intended Use:** An implantable Hemostatic clip intended for the ligation of blood vessels.

**Device Description:** The clips are composed exclusively of titanium and are supplied sterile in various sizes (small, medium, medium/large, and large) six clips per disposable holder. The titanium used meets all the requirements of the American Society for Testing and Materials (ASTM) standard specification F-67 95 "Unalloyed Titanium for Surgical Implant Applications", Grade I.

**Predicate Devices:** Baxter Healthcare Vitaclip® K953258, Edward Weck & Company, Pre-amendment Hemoclip® Surgical Occluding System and Hemoclip® Surgical Occluding Clip Stainless Steel K800079, United States Surgical Corporation, Auto Suture® Titanium Hemostatic Clip K853650 and Axiom Auto-Clip® K771021.

**Comparison of Technological Characteristics:** The titanium clip material is identical to the predicate devices. In function, the clips are the same as the predicate devices. The disposable holder is a polycarbonate plastic equivalent to the predicate devices.

**Safety and Efficacy Information:** The titanium itself is well recognized as being safe and effective for long term implant. The millions of clips applied yearly and the years in use (since 1963) attest to the wide acceptance of this method of Hemostatic control.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Ellen J. Henke-Knupp  
Official Correspondent  
EISNER USA  
15 Caswell Lane  
Boatyard Square  
Plymouth, Massachusetts 02332

OCT 21 1997

Re: K972745  
Trade Name: Titanium Hemostatic Clip  
Regulatory Class: II  
Product Codes: MCH and FZP  
Dated: July 17, 1997  
Received: July 23, 1997

Dear Ms. Henke-Knupp:

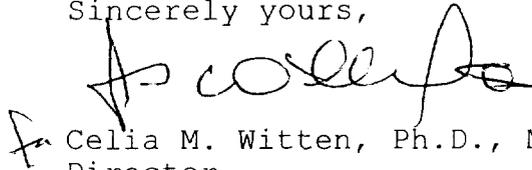
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K 972745

Device Name: Titanium Hemostatic Clip

Indications For Use:

The EISNER USA Hemostatic Clip is designed for the intended use of ligating blood vessels. The clip has been specially designed to insure occlusion of vessels and prevent any slippage once applied. The clip has applications in many types of surgical procedures where hemostasis is required or radiographic marking is necessary.

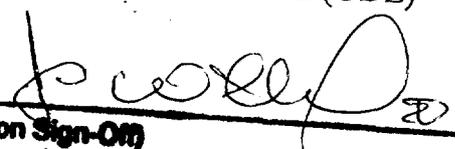
As the clip is made of Commercially Pure - GRADE I, Implant Titanium (/ASTM Standard F-67 95), it has low magnetic susceptibility and is safe for use in the present clinical MRI environment with main Magnetic fields up to 2 Tesla and maximum main field gradients up to 500 gauss per centimeter. The Magnetic Force will only approach gravitational force for MR Systems above 15 T.

As the clip is made of Commercially Pure - GRADE I, Implant Titanium (/ASTM Standard F-67-95), it also produces less artifact and better resolution of anatomic structures than non-titanium clips in CT Scanning.

Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The EISNER USA Clip can be left in vivo without sequela as it is biologically inert.

(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 General Restorative Devices  
510(k) Number

K972745

Prescription Use   
(Per 1 CFR 801.109)

OR

Over-The-Counter Use