OCT 13 1998

K981645

510(k) Summary / Statement

Submitters Name: **VITALITEC INTERNATIONAL, Inc.**
15 Caswell Lane, 3rd. Fl.
Plymouth, MA 02360
Ph: 508-747-6033 Fax: 508-747-5118

Contact Name: Ellen Henke-Knupp, Regulatory Director

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
Hemostatic Clip	# 79 MCH 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.
ISO 5832 - 2- 93, 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 (mini-micro, micro, small, small/medium, 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 and International Organization Standard , ISO 5832-2-93 "Implants for Surgery - Metallic Materials -Part 2: Unalloyed Titanium".

Predicate Devices: EISNER USA Titanium Hemoclip K972745, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1998

Ms. Ellen Henke-Knupp
Regulatory Director
Vitalitec International, Inc.
15 Caswell Lane
3rd Floor
Plymouth, Massachusetts 02360

Re: K981645
Trade Name: Implantable Titanium Hemostatic Clip
Regulatory Class: II
Product Code: FZP
Dated: August 14, 1998
Received: August 17, 1998

Dear Ms. Henke-Knupp:

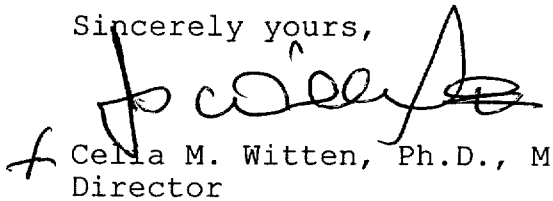
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 premarket 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,



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

K981645

510(k) Number (if known): K 981645

Device Name: Implantable Titanium Hemostatic Clip

Indications For Use:

The VITALITEC INTERNATIONAL, INC,. Hemostatic Clip is designed for the intended use of ligating blood vessels. The clip has been specially designed to insure occclusion 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.

Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The VITALITEC INTERNATIONAL, INC., 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 K981645

Prescription Use X
(P 1 CFR 801.109) OR Over-The-Counter Use