K971588

OCT 24 1997

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K971588

Applicant Information:

Date Prepared:	April 28, 1997
Name:	Elective Vascular Intervention EVI)
Address:	2915 McClure Oakland, California 94609 510-834-1210
Contact Person:	Michael A. Daniel
Phone Number:	(415) 237-7036
Facsimile Number:	(415) 526-2060

Device Information:

Classification:	Class I (Exempt) Clip Applier Class II Implantable Clips
Trade Name:	EVI Sutured-Clip™ Applier EVI Sutured-Clip™
Common Name:	Implantable Clip, Vascular Clip, Vascular/Hemostatic Clip Applier
Classification Name:	Surgical Devices: Implantable Clip, 21 CFR 878.4300 Cardiovascular Prosthetic Devices: Vascular Clip, 870.3250

Predicate Devices:

The Elective Vascular Intervention (EVI) Sutured-Clip™ and Sutured-Clip™ Applier is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1.	Pilling Weck	Hemoclip S15 Automatic Applier
2.	U.S. Surgical	ENDO CLIP Applier
3.	Ethicon	LIGACLIP Endoscopic Clip Applier

Device Description:

The Elective Vascular Intervention (EVI) Sutured-Clip™ and Clip Applier is a single fire applier that applies EVI Sutured-Clips™ for vascular anastomsis and tissue approximation applications. The Sutured-Clip consists of a vascular clip with a needle swaged or connected to one end. This design allows precise placement of clips prior to closure. The device is fabricated from standard medical and implantable grade materials.

510(k) SUMMARY

(Continued)

Intended Use:

The Elective Vascular Intervention (EVI) Sutured-Clip™ and Clip Applier is intended for use in endoscopic and non-endoscopic creation and repair of arteriovenus fistulae and the creation of everting anastomoses in blood vessels, grafts and other tubular structures and in the approximation of other soft tissue structures.

Comparison to Predicate Device(s):

The Elective Vascular Intervention (EVI) Sutured-Clip™ Clip and Clip Applier are substantially equivalent to the US Surgical VCS Clip and Clip Applier in terms of intended use. Both devices are intended for application of vascular clips to everted tissue for purposes of performing vacular anastomosis. The EVI Sutured-Clip and Clip Applier is substantially equivalent to the Ethicon LIGACLIP Clip and Clip Applier in terms of the single clip application option.

The System differs from the currently marketed predicate devices in that the Sutured-Clips™ have a needle swaged on to one end to facilitate precise placement. In this regard it is similar to currently marketed suture needles.

In Vitro Test Data:

Design analysis and *in vitro* data confirm that basic functional characteristics are substantially equivalent to the predicate devices sited. Testing included evaluation of mechanical integrity and the force required to open or dislodge clip. All data fell well within both internal specification requirements as well as external standard requirements and predicate performance expectations.

Summary:

Based upon the product technical information provided, intended use, performance and biocompatibility information provided in this pre-market notification, the EVI Sutured-Clip™ and Sutured-Clip™ Applier has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael A. Daniel
EVI Elective Vascular Intervention
2915 McClure
Oakland, California 94609

OCT 24 1997

Re: K971588
Trade Name: EVI Sutured-Clip™ and Sutured-Clip™ Applier
Regulatory Class: II
Product Code: FZP
Dated: September 14, 1997
Received: September 17, 1997

Dear Mr. Daniel:

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 requirements , 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

510(k) Number (if known): K971588

Device Name: **Elective Vacular Intervention (EVI) Sutured-Clip™ Applier**

Indications For Use:

The Elective Vascular Intervention (EVI) Sutured-Clip™ and Sutured-Clip Applier™ are intended for endoscopic and non-endoscopic use in the creation of everting anastomoses in blood vessels, grafts and other tubular structures.

(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 K971588

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)