JUN 11 1999

K991002

SECTION 6
510(k) SUMMARY

Submitter Name:	Pacific Surgical Innovations, Inc.
Submitter's Address:	360 Industrial Road, Unit H San Carlos, CA 94070
Contact Person:	Terry Johnston, President
Phone Number:	650-802-6988
Facsimile Number:	650-802-0120
Date Prepared:	March 12, 1999
Device Trade Name:	PSI Titanium Micro-Ligation Hemostatic Clip
Device Common Name:	Micro-Ligation Hemostatic Clip
Classification Name:	Implanted Malleable Clip
Predicate Device:	Vitalitec International Titanium Hemostatic Clip Spetzler Titanium Aneurysm Clip
Device Description:	Bent titanium wire that is forcibly closed to occlude an intracranial blood vessel, stop bleeding, or hold tissue or mechanical device in place in a patient. Especially designed to prevent slippage when properly applied.
Intended Use:	The Pacific Surgical Innovations, Inc. Titanium Micro-Ligation Hemostatic Clip is designed for temporary or permanent implantation for use in ligating blood vessels. The clip has applications in many surgical procedures including where hemostasis is required or radiographic marking is necessary, in general or intracranial procedures.

Technological Characteristics and Comparison to Predicate	The PSI Titanium Micro-Ligation Hemostasis Clip is manufactured from the same materials, meeting the same standards and dimensional specifications and manufactured by the same contract manufacturer as the prdicate hemostasis clip.
Performance Data:	When used with the appropriate clip applier, as used with the predicate device, the PSI hemostasis clip functions in the same manner as the predicate device in occluding blood vessels.
Conclusion:	The PSI Titanium Micro-Ligation Hemostatic Clip is safe and effective for its intended use and meets all regulatory requirements to be found substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Mr. Terry Johnston
President
Pacific Surgical Innovations, Inc.
360 Industrial Road, Unit H
San Carlos, California 94070

Re: K991002
Trade Name: Titanium Micro-Ligation Hemostatic Clip
Regulatory Class: II
Product Code: FZP
Dated: March 19, 1999
Received: March 25, 1999

Dear Mr. Johnston:

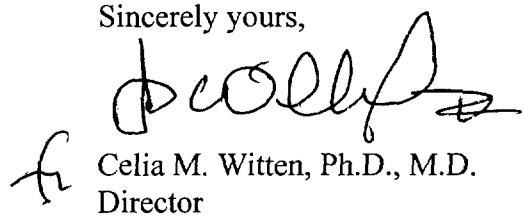
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K991002

SECTION 5

INDICATIONS FOR USE

PSI Titanium Micro-Ligation Hemostatic Clip

Temporary or Permanent Occlusion of Blood Vessels Including Intracranial Blood Vessels

(Division Sign-Off)
Division of General Restorative Devices K991002
510(k) Number

Prescription Use X
(Per 21 CFR 801.109)