K991959

JAN - 6 2000

SECTION 6
510(k) SUMMARY

Submitter Name:	Pacific Surgical Innovations, Inc.
Submitter's Address:	360 Industrial Road San Carlos, CA 94070
Contact Person:	Terry Johnston, President
Phone Number:	650-802-6988
Facsimile Number:	650-802-0120
Date Prepared:	April 15, 1999
Device Trade Name:	PSI Titanium Aneurysm Clip
Device Common Name:	Aneurysm Clip
Classification Name:	Aneurysm Clip, 21 CFR 882.5200
Predicate Device:	Aesculap Titanium Aneurysm Clip (K983758) Taka Aneurysm Clip (K972750)
Device Description:	Bent titanium wire which provides a spring operated, self Closing aneurysm clip of various lengths/sizes.
Intended Use:	Placement in the intracranial space for the occlusion of a cerebral aneurysm (a balloon like sac formed on a blood vessel) to prevent it from bleeding or bursting. Placement of the clip requires the use of especially designed appliers
Technological Characteristics And Comparison to Predicate	The PSI Titanium Aneurysm Clip is manufactured from the same materials, to equivalent functional and dimensional specifications as the predicate clips. The material composition is titanium alloy (Ti-6Al-4V). The alloy composition and properties conform with ISO Standard 5832/3: "Implants for Surgery Metallinc Materials – Part 3: WroughtTitanium 6 – Aluminum 4 – Vanadium Alloy" and ASTM Standard F – 136: "Specification for Wrought Titanium 6AL-4V ELI Alloy for Surgical Applications". The PSI clips share similar tolerances, manufacturing controls, packaging and labeling as the predicate Taka clips.

K991959

Performance Data:	When used with the appropriate clip applier, as with the predicate device, the PSI Titanium Aneurysm Clip functions in the same manner as the predicate device in the occlusion of cerebral aneurysms. When used in the MRI environment, the device presents no additional risk to the patient or other personnel, is compatible with current diagnostic imaging equipment and provides substantially reduced image artifacts over cobalt-based predicate clips.
Conclusion:	The Titanium Aneurysm Clip is safe and effective for it's 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

NOV 21 2006

Pacific Surgical Innovations, Inc.
% Mr. Terry Johnston
Vice President and General Manager
360 Industrial Road, Unit H
San Carlos, California 94070

Re: K991959
Trade/Device Name: Titanium Aneurysm Clip
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm clip
Regulatory Class: II
Product Code: HCH, HCI
Dated: October 28, 1999
Received: November 1, 1999

Dear Mr. Johnston:

This letter corrects our substantially equivalent letter of January 6, 2000.

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 (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.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

For Peter Pinsky DRP Director

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

Enclosure

K991959

SECTION 5

INDICATIONS FOR USE

Device Name: **PSI TITANIUM ANEURYSM CLIP**

Indication for Use: **Permanent placement in the brain for occlusion of cerebral aneurysms. They are only to be applied with PSI clip appliers with titanium alloy jaw inserts**

Prescription Use ___X___ OR Over the Counter _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991959