K993019

MAR 3 0 2000

SECTION 6

510(k) STATEMENT

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:	August 26, 1999
Device Trade Name:	Pacific Surgical Patties
Device Common Name:	Cottonoid Pattie
Classification Name:	Cottonoid Paddie
Predicate Device:	Codman Surgical Patties
Device Description:	A cotton pad used during surgery to protect nervous tissue, absorb fluids or stop bleeding.
Intended Use:	The Pacific Surgical Patties are intended for use in neurosurgical procedures to protect tissue, absorb fluids and stop bleeding. They are supplied to the user in sterile packages. These patties are X-ray detectable and are provided in a variety of sizes necessary to meet clinical needs.
Technological Characteristics and Comparison to Predicate:	The Pacific Surgical Patties are manufactured from equivalent materials meeting the same or similar standards, dimensional specifications and quality conditions as the predicate device.
Performance Data:	Pacific Surgical Patties provide X-ray detectable sterile patties that absorb fluids at 6.5 times its dry weight and functions in the same manner as the predicate.

Conclusion:	The Pacific Surgical Patties are as 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

MAR 3 0 2000

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

Re: K993019
Trade Name: Surgical Patties
Regulatory Class: II
Product Code: HBA
Dated: March 13, 2000
Received: March 13, 2000

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

K993019

SECTION 5

INDICATIONS FOR USE

Device Name: **Pacific Surgical Patties**

Indications for Use: **To be used in surgery to protect nervous tissue, absorb fluids, or stop bleeding.**

NPO for cmw

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993019

Prescription Use _____ OR Over the Counter _____