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A. 510(k) Summary

SUBMITTER:

Incisive Surgical Inc.
1409 Fairfield Road
Minnetonka, MN 55305
Phone: 952-591-2543
Fax: 952-591-5989

CONTACT PERSON:

Jim Peterson
Vice President, Regulatory and Quality Affairs

DATE PREPARED: December 12, 2002

TRADE NAME: INSORB™ Absorbable Staple

COMMON NAME: Implantable Staple

CLASSIFICATION: 21 CFR 878.4750, Staple, Implantable
Class II

PRODUCT CODE: GDW

PREDICATE DEVICE(S): The INSORB™ Absorbable Staple is substantially equivalent to the Autosuture Absorbable Subcuticular Closure Staple manufactured by United States Surgical (K915489), the Proximate Absorbable Staple manufactured by Ethicon Inc. (K915693), and Vicryl Synthetic Absorbable Suture which are also manufactured by Ethicon Inc. (Multiple 510(k)'s *e.g* K022269, K974299, K962480).

DEVICE DESCRIPTION: INSORB™ Absorbable Staples are 5.1mm in length, 0.79mm thick, 3.48mm wide overall, and have barb tips that are 0.66mm apart. They are used in conjunction with a manual surgical stapler from Incisive (Note: Incisive's manual surgical stapler is a Class I exempt device pursuant to 21 CFR 878.4800 and is not the subject of this submission).

INSORB™ staples are made from an absorbable copolymer which is a synthetic polyester derived from lactic and glycolic acids. It is chemically similar to other surgical glycolide/lactide-based copolymers. Polyglycolic/polylactic acid copolymers degrade *in vivo* by hydrolysis to glycolic acid and lactic acid which are then absorbed and metabolized by the body.

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INTENDED USE: Synthetic absorbable INSORB™ staples are intended for use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

FUNCTIONAL & SAFETY TESTING: Prior to commercialization INSORB™ Absorbable Staples underwent testing to verify appropriate functional characteristics. This testing included an animal study, mechanical performance testing, and package testing. This testing demonstrates that the INSORB™ Absorbable Staples meet all required specifications.

CONCLUSION: The INSORB™ Absorbable Staples from Incisive are substantially equivalent to the Autosuture Absorbable Subcuticular Closure Staple manufactured by United States Surgical (K915489), the Proximate Absorbable Staple manufactured by Ethicon Inc. (K915693), and Vicryl Synthetic Absorbable Suture which are also manufactured by Ethicon Inc. (Multiple 510(k)'s *e.g* K022269, K974299, K962480).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Mr. Jim Peterson
Vice President, Regulatory
and Quality Affairs
Incisive Surgical, Inc.
1409 Fairfield Road
Minnetonka, Minnesota 55305

Re: K024117
Trade/Device Name: INSORB™ Absorbable Staple
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 2, 2003
Received: April 8, 2003

Dear Mr. Peterson :

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 application (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 such 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 begin 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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Page

Device Name:
INSORB™ Absorbable Staple

Indications For Use:
Synthetic absorbable INSORB™ staples are intended for use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024117