K061784

Exhibit I

JUL 26 2006

510(k) Summary

Submitter:	Incisive Surgical 14405 21st Avenue North, Suite 130, Plymouth, MN 55447-2000
Contact Person:	James Peterson, Vice President, Ph: (952) 591- 2543 ext 14
Date Prepared:	June 22, 2006
Trade Name:	INSORB™ Absorbable Staple
Classification	Class II, 21 CFR 8787.4750, Staple, Implantable
Product Code:	GDW
Predicate Device and 510(k) No.	INSORB™ Absorbable Staple K033602
Device Description:	INSORB™ Absorbable Staples are 5 mm in length, 0.8 mm thick, 3.5 mm wide overall, and have cleat tips that are 0.7 mm 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).
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.
Statement of Technological Comparison	The subject device and the predicate device are identical except for: 1) Sterilization Validation changed from VDmax to Method 1 to allow implementation of a 10^{-6} SAL validated gamma dose at less than 25kGy. 2) Packaging includes a desiccant. 3) Strength specifications for the staple following exposure to 37°C buffered saline for 7 days and 21 days have been increased 50% to accommodate the STRONGER staple fabricated by the refinements in the micromolding process, the lower gamma dose possible under a Method 1 validation, and the storage benefits of including a desiccant within the packaging. 4) Shelf Life extended to 2 years.
Conclusion:	The modified INSORB Absorbable Staple described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Incisive Surgical, Inc.
% Mr. James Peterson
Vice President
14405 21st Avenue North, Suite 130
Plymouth, Minnesota 55447-2000

Re: K061784
Trade/Device Name: INSORB™ Absorbable Staple
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 22, 2006
Received: June 29, 2006

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 (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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): **K061784**

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.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K061784