Exhibit F: 510(k) K120373 Summary

MAR 16 2012

Submitter:	Incisive Surgical 14405 21st Avenue North, Suite 130, Plymouth, MN 55447-2000
Contact Person:	David B. Herridge, Vice President, Ph: (952) 591- 2543 ext. 19
Date Prepared:	February 3, 2012
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 K090159
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 0.8 mm apart. They are used in conjunction with a manual surgical stapler from Incisive Surgical Inc. (Note: manual surgical stapler is a Class I exempt device pursuant to 21 CFR 878.4800 and is not the primary subject of this submission).
Intended Use:	Synthetic absorbable INSORB staples are intended 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. This Special 510(k) seeks only to more clearly communicate the device's intended use for the subcuticular closure of skin.
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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

Incisive Surgical
% Mr. David B. Herridge
Vice President
14405 21st Avenue North, Suite 130
Plymouth, Minnesota 55447-2000

Re: K120373
Trade/Device Name: INSORB® Absorbable Staple
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 01, 2012
Received: March 05, 2012

Dear Mr. Herridge:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Exhibit D: Indications for Use

510(k) Number (if known):	K120373
Device Name	INSORB® Staple
Indications for Use	Synthetic absorbable INSORB staples are intended for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

Prescription Use__X__ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120373