K110512

MAR 2 3 2011

Attachment F

510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Submitter / Contact Person / Date of Preparation

Submitter	Zyga Technology, Inc. 700 10th Ave South Minneapolis, MN 55415-1745
Contact Person	Diane Brinza Director of Regulatory and Clinical Ph. 612.455.1061, ext. 104 Fax. 612.455.1064
Date of Preparation	February 21, 2011

2. General Information

Trade Name	SImmetry™ Sacroiliac Joint Fusion System
Common / Usual Name	Fixation Device/Bone Screw
Classification Name	Smooth or threaded metallic bone fixation fastener
Classification	Class II (per 21 CFR § 888.3040)
Manufacturer	Zyga Technology, Inc. 700 10th Ave South Minneapolis, MN 55415-1745
Identification of Predicate Devices	K102907 Zyga Technology, Inc. SImmetry™ Sacroiliac Joint Fusion System

Device Description	The SImmetry™ Sacroiliac Joint Fusion System consists of cannulated screws available in titanium having diameters ranging from 6.5mm-12.5mm; and lengths of 30mm-70mm; titanium washers are available for the 6.5mm diameter screws. The revised surgical technique manual for the new modified version of the SImmetry™ Sacroiliac Joint Fusion System contain instructions for adding autologous graft material to the sacroiliac joint to help ensure fusion.
Intended Use / Indications for Use	The SImmetry™ Sacroiliac Joint Fusion System is intended for fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.
Technological Characteristic	The principle of operation and fundamental scientific technology of the subject devices is identical to that of the identified predicate.
Materials	The subject devices are manufactured from Titanium Alloy (Ti-6Al-4V ELI).
Technological Comparison	The modification of the SImmetry™ Sacroiliac Joint Fusion System does not represent a change in technological characteristics from that of the indicated predicate device, and therefore does not raise any new questions of safety or effectiveness.
Summary of Non-clinical Performance Data	The modification from the previous version of this device does not affect the intended use or alter the fundamental scientific technology or performance of the device when compared to the identified predicate. The addition of autologous graft material to the sacroiliac joint does not require testing to ensure substantial equivalence to the unmodified device.
Conclusion	Equivalence for the SImmetry Sacroiliac Joint Fusion System is based on the same indications for use, design features, operational principles, and material composition and mechanical performance when compared to the predicate device cleared under K102907.

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

Zyga Technology, Inc.
% Ms. Diane Brinza
Director of Regulatory and Clinical
700 10th Avenue South, Suite 400
Minneapolis, Minnesota 55415

MAR 2 3 2011

Re: K110512
Trade/Device Name: SImmetry Sacroiliac Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: February 21, 2011
Received: February 23, 2011

Dear Ms. Brinza:

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,

for

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

Enclosure

K110512

~~Attachment A~~

Indications for Use Statement

510(k) Number (if known)

Device Name SImmetry Sacroiliac Joint Fusion System

Indications for Use

The SImmetry™ Sacroiliac Joint Fusion System is intended for fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X____
(Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110512

~~Confidential~~

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