



Food and Drug Administration
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August 5, 2015

Zyga Technology, Incorporated
Ms. Diane Brinza
Director of Regulatory Affairs
5600 Rowland Road, Suite 200
Minnetonka, Minnesota 55343

Re: K151818

Trade/Device Name: Slimmetry[®] 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: July 3, 2015
Received: July 6, 2015

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151818

Device Name

SImmetry® Sacroiliac Joint Fusion System

Indications for Use (Describe)

The SImmetry® Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92(c)]

Date of Preparation	July 3, 2015
Submitter' Name and Address	Zyga Technology, Inc. 5600 Rowland Road, Suite 200 Minnetonka, MN 55343
Contact Person	Diane Brinza Director of Regulatory Affairs Ph. 952-698-9959 Fax. 952-698-9940 dbrinza@zyga.com
Proprietary Name	SImmetry® Sacroiliac Joint Fusion System
Common / Usual Name	Sacroiliac Joint Fixation Bone Screw
Classification	Class II per 21 CFR Part 888.3040 Smooth or threaded metallic bone fixation fastener Division of Orthopedic Devices
Product Code	OUR
Manufacturer	Zyga Technology, Inc. 5600 Rowland Road, Suite 200 Minnetonka, MN 55343
Predicate Device	K141549 SImmetry Sacroiliac Joint Fusion System
Device Description	<p>The SImmetry Sacroiliac Joint Fusion System consists of sterile packaged partially threaded or fully threaded, self-tapping cannulated titanium implants designed to transfix the sacrum and ilium, providing stability for bony fusion. The surgical implants are available in various sizes to accommodate patient anatomy. Implants have major diameters ranging from 6.5mm-14.5mm, in 2mm increments. Lengths in 5mm increments range from 30mm-110mm for fully threaded implants and 50mm to 110mm for partially threaded implants. All partially threaded implants and 6.5mm diameter fully threaded implants have a pre-assembled washer. Individually sterile packaged washers are available for fully threaded implants having diameters ranging from 8.5mm-14.5mm.</p> <p>All devices are manufactured from Titanium Alloy (Ti-6Al-4V ELI).</p>

Indication for Use	The SImmetry Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.
Performance Data	No performance data is required to support this Special 510(k).
Technology	This Special 510(k) does not involve any changes to the technological characteristics of the device. The principle of operation of the subject device is identical to that of the predicate device cleared under K141549, SImmetry Sacroiliac Joint Fusion System.
Substantial Equivalence Conclusion	Equivalence for the SImmetry System is based on similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under K141549, SImmetry Sacroiliac Joint Fusion System.