K121148

510(k) Summary

AUG 2 0 2012

Submitter:	Medical Designs LLC 6709 S. Minnesota Ave. Suite 204 Sioux Falls, SD 57108-2593
Contact Person:	Kristi Vondra Vice President of Operations Telephone: (605) 275-1032 Fax: (605) 335-3734 e-mail: kvondra@medicaldesignsllc.com
Date Prepared:	April 13, 2012
Trade Name:	SAMBA™ Screw System
Classification:	Class II, Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Product Code:	HWC, OUR
Predicate Device(s):	The subject device is equivalent to the following devices: • Synthes 6.5mm Cannulated Screw (K021932) • SI-LOK Sacroiliac Joint Fixation System (K112028)
Device Description:	The SAMBA screw is a cannulated metallic bone screw designed to stabilize the sacroiliac (SI) joint. The SAMBA screw is composed of implant-grade Titanium, Ti-6Al-4V ELI, conforming to ASTM F-136. The SAMBA screw is 9 mm in diameter and offered in 25-50 mm lengths with multiple longitudinal slots on its shaft. Each slot set consists of four (4) holes oriented 90 degrees apart around the circumference of the screw at specified axial location. It will be provided as sterile, single units packaged in a sealed tray and pouch. The screw is a single use device and is not intended to be resterilized.
Intended Use:	The SAMBA™ Screw System is intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature patients.
Functional and Safety Testing:	To verify that device design met it's functional and performance requirements, representative samples of the device underwent mechanical testing for static axial pull out strength, static torsion, static cantilever bending, and dynamic cantilever bending in accordance with the following standards: • ASTM F2193-02 (2007) Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System • ASTM F543-07 Standard Specification and Test Methods for Metallic Medical Bone Screw
Conclusion:	Medical Designs considers the SAMBA Screw System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

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

AUG 2 0 2012

Medical Designs, LLC.
% Kristi Vondra
Vice President of Operations
6709 S. Minnesota Ave. Suite 204
Sioux Falls, South Dakota 57108-2593

Re: K121148
Trade/Device Name: SAMBA™ Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: July 16, 2012
Received: July 19, 2012

Dear Ms. Kristi Vondra:

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

K121148

4. Indications for Use Statement

Device Name: SAMBA™ Screw System

Indications for Use:

The SAMBA™ Screw System is intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature patients.

Prescription Use ___X___ (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121148