



January 25, 2019

Biofusion Medical
% Daniel Lanois
Principal Consultant
SurgOp Support LLC
7512 Lancaster Gate
Frisco, Texas 75035

Re: K182919

Trade/Device Name: SI-Restore® Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: December 21, 2018
Received: December 26, 2018

Dear Daniel Lanois:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill -
 for MNM

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)

K182919

Device Name

SI-Restore® Sacroiliac Joint Fixation System

Indications for Use (Describe)

The Biofusion Medical SI-Restore® Sacroiliac Joint Fixation 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (as required by 21 CFR 807.92)

Date Prepared	October 18, 2018		
Manufacturer	Biofusion Medical LLC		
Address	2503 Cedarview Drive, Austin, Texas 78704		
Telephone	866-489-0602		
Fax	866-441-5351		
Contact Person	Daniel Lanois Consultant		
Address	SurgOp Support LLC 7512 Lancaster Gate, Frisco, Texas 75035		
Telephone	678-371-3605		
Fax			
Email	daniel@surgopsupport.com		
Trade Name	SI-Restore® Sacroiliac Joint Fixation System		
Common Name	Bone Screw or Internal Fixation Device		
Panel Code	Orthopedic/87		
Classification Name	Smooth of threaded metallic bone fixation fastener		
Class	Class II		
Regulation Number	21 CFR 888.3040		
Product Code	OUR		
Name of Predicate Device	510(k) #	Manufacturer	
SI-LOK™ Sacroiliac Joint Fixation System	K112028	Globus Medical	
Description	The SI-Restore® Sacroiliac Joint Fixation System consists of a cannulated titanium (Ti 6Al4V ELI, per ATSM F136) screw with a titanium (Ti 6Al4V ELI, per ATSM F136) washer affixed to the head of the screw for full cortex engagement. The Implant is designed to prevent motion of the sacroiliac (SI) joint. The delivery system uses guide pins for accurate preparation for and placement of the implant.		
Indications and Intended Use	The Biofusion Medical SI-Restore® Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.		
Technological Characteristics/ Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, is substantially equivalent to the Predicate. The Subject device is substantially equivalent to the Predicate device in intended use, indications for use, materials, technological characteristics, and labeling.		
Performance Data	Static Axial Pull-out and Static Torque to Failure testing (per ASTM F543-13) confirmed that the Subject device performed as intended. Also, Static Three-Point Bending and Dynamic Three-Point Bending (per ASTM F1264-14) confirmed that the Subject device performed as intended.		
Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and comparison to Predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed Predicate devices.		