DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2015

SI-TECHNOLOGY, LLC
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K151462
Trade/Device Name: SI-TECHNOLOGY® SI-DESIS® Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR, HWC
Dated: May 22, 2015
Received: June 1, 2015

Dear Dr. Braddon:

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,

Mark N. Melkerson -S

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

Enclosure

5 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement on last page.*

510(k) Number *(if known)*
K151462

Device Name
SI-TECHNOLOGY® SI-DESIS® Screws

Indications for Use *(Describe)*

The SI-TECHNOLOGY Device is intended for sacroiliac joint fusion for conditions including sacroiliac (SI) 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)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the SI-TECHNOLOGY® SI-DESIS® Screws is provided below.

Date Summary Prepared	July 30, 2015
Manufacturer/Distributor/Sponsor	SI-TECHNOLOGY, LLC 320 East Vine Drive, Suite 217 Fort Collins, Colorado 80524 Phone: 970-422-1212
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 LGB@SecureBME.com
Trade Name	SI-TECHNOLOGY® SI-DESIS® Screws
Common Name	Smooth or threaded metallic bone fixation fastener
Code –Classification	OUR, HWC 21 CFR 888.3040 : Class II
Predicate Devices	K112028 – Globus SI-LOK Sacroiliac Joint Fixation System K021932 - Synthes 6.5 mm Cannulated Screw
Device Description	The SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System consists of screws designed to assist in the healing of sacroiliac joints for fusion by providing fixation of large bones and large bone fragments of the pelvis. The screws are **not** intended to replace normal body structures. The screws are offered in 6.5 mm diameter cannulated, partially threaded or fully threaded configurations in various lengths. Additionally, optional supplemental 5 mm diameter screws are offered in various lengths and are to be used **only** in conjunction with the 6.5 mm screws for supplemental screw fixation to accommodate patient anatomy. The screws are manufactured from titanium alloy per ASTM F136.
Indications for Use	The SI-TECHNOLOGY® SI-DESIS® Device is intended for sacroiliac joint fusion for conditions including sacroiliac (SI) joint disruptions and degenerative sacroiliitis.
Technological Characteristics	As was established in this submission, the subject SI-TECHNOLOGY® SI-DESIS® Screws are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

Non-Clinical Performance Testing Conclusion	Non-clinical testing was performed to demonstrate the SI-TECHNOLOGY® SI-DESIS® Screw System is substantially equivalent to other predicate devices. In order to demonstrate the substantial equivalence, the following tests were performed: • Screw strength via ASTM F543 • Static and Fatigue testing via ASTM F2193 The results of these studies show the subject SI-TECHNOLOGY® SI-DESIS® Screws meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent.
Substantial Equivalence Summary (Conclusion)	Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject SI-TECHNOLOGY® SI-DESIS® Screws has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.