May 21, 2018

Spinal Analytics & Geometrical Implant Co, LLC
James J. Gibson Jr., CPA, Ph.D.
SAGICO Project Manager
2189 West Busch Boulevard
Tampa, Florida 33612

Re: K180220
Trade/Device Name: SAGICO OSI SPINAL SYSTEM by Osimplant
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: February 8, 2018
Received: February 9, 2018

Dear Dr. Gibson:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Ronald P. Jean -S

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

Enclosure

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 below.

510(k) Number *(if known)*

K180220

Device Name

SAGICO OSI SPINAL SYSTEM by Osimplant

Indications for Use *(Describe)*

The SAGICO OSI SPINAL SYSTEM by Osimplant is intended for use in the non-cervical spine.

When used for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the SAGICO OSI SPINAL SYSTEM by Osimplant is intended to provide additional support during fusion using autograft or allograft in Skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the SAGICO OSI SPINAL SYSTEM by Osimplant implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The SAGICO OSI SPINAL SYSTEM by Osimplant for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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.

510(k) Summary

Device Trade Name(s):	SAGICO OSI SPINAL SYSTEM by Osimplant
Classification Panel:	Orthopedic
Common Name:	Pedicle Screw Spinal System
Class and Reference:	Class II
Product Code(s):	NKB, KWQ, KWP
Classification Name(s):	Thoracolumbosacral Pedicle Screw System (NKB) Class II per 21 CFR §888.3070 Appliance, Fixation, Spinal Intervertebral Body (KWQ) Class II per 21 CFR §888.3060 Appliance, Fixation, Spinal Interlaminal (KWP) Class II per 21 CFR §888.3050
Applicant/Official Contact Person:	James J. Gibson, Jr., CPA, PhD SAGICO Project Manager Email: JG@Sagico.com Tel. (813) 830-3636 / Fax (813) 433-5586
Submitter /Manufacturer:	Spinal Analytics & Geometrical Implant Co, LLC dba/ SAGICO 2189 West Busch Blvd Tampa, Florida 33612 Tel. (813) 830-3636 / Fax (813) 433-5586
Preparation Date:	May 18th, 2018

Predicate Devices

The subject device is substantially equivalent to the primary predicate device XIA® 3 Spinal System – Stryker Spine (K113666) and additional predicate devices, USS Small Stature System - Synthes Spine Medtronic Spine (K071373), CD HORIZON Spinal System - Sofamor Danek USA (K091445), TSRH Spinal System - Sofamor Danek USA (K994121), XIA 3 Spinal System - Stryker Spine (K111492)

Purpose:
The purpose of this submission is to request clearance for new system "SAGICO OSI SPINAL SYSTEM by Osimplant".

Device Description:

The SAGICO OSI SPINAL SYSTEM by Osimplant constructs of monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking cap set screws, rods, hooks, monoaxial and mutltiaxial transverse connectors and associated surgical instruments. The SACICO OSI SPINAL SYSTEM by Osimplant implants are available in a variety of sizes to accommodate individual patient anatomy and pathology conditions. SAGICO OSI SPINAL SYSTEM by Osimplant implants are designed to adapt 5.5mm diameter rods; the implants are manufactured from Ti6A14V alloy and offered in a sterile package option.

Indications for use:

The SAGICO OSI SPINAL SYSTEM by Osimplant is intended for use in the non-cervical spine. When used for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the SAGICO OSI SPINAL SYSTEM by Osimplant is intended to provide additional support during fusion using autograft or allograft in Skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
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- Trauma (i.e. fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the SAGICO OSI SPINAL SYSTEM by Osimplant implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The SAGICO OSI SPINAL SYSTEM by Osimplant for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Technological Characteristics:
Testing performed on SAGICO OSI SPINAL SYSTEM by Osimplant included in this submission demonstrates that the SAGICO OSI SPINAL SYSTEM by Osimplant is substantially equivalent to predicate devices cleared by FDA for commercial distribution in the United States market. The SAGICO OSI SPINAL SYSTEM by Osimplant substantial equivalence determination to the predicate systems is based on comparable data drawn from design, labeling, and indications for use, function and implant materials.

Performance data:
Non-clinical performance data testing conducted to support substantial equivalence for the SAGICO OSI SPINAL SYSTEM by Osimplant device included:

ASTM F1717-04
Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

- Static Compression Bending Test
- Dynamic Compression Bending Test

ASTM F1798-13
Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants

- Axial Gripping Test
- Axial Torsion Gripping Test
- Flexion Extension Static Test

Basis of Substantial Equivalence:
The SAGICO OSI SPINAL SYSTEM by Osimplant has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject and predicate devices.

Conclusion:
The SAGICO OSI SPINAL SYSTEM by Osimplant has been shown to be substantially equivalent to legally marketed predicate devices with respect to its indications for use, design, function, and materials.