October 23, 2023

Sagico VA USA, LLC
James Gibson, PhD
President
2189 West Busch Blvd.
Tampa, Florida 33612

Re: K232561
Trade/Device Name: Ripley Spinal Screw System by SAGICO
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: August 18, 2023
Received: August 24, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232561

Device Name
Ripley Spinal Screw System by SAGICO

Indications for Use *(Describe)*
The RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.
The RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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.

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

Device Trade Name(s):	Ripley Spinal Screw System by SAGICO
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., PhD, CPA, SAGICO VA USA, LLC, Project Manager Email: JG@SAGICOUSA.com Tel. (813) 815-0613
Submitter /Manufacturer:	SAGICO VA USA, LLC 2189 West Busch Blvd Tampa, Florida 33612 Tel. (813) 815-0613
Preparation Date:	August 18, 2023

Predicate Devices :

The subject device is substantially equivalent to the primary predicate device: SAGICO OSI SPINAL SYSTEM by Osimplant (K180220), the 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 the system known as the "RIPLEY SPINAL SCREW SYSTEM BY SAGICO".

SAGICO VA USA SPINAL SYSTEM
TRADITIONAL 510(K) PREMARKET NOTIFICATION

Device Description:

The RIPLEY SPINAL SCREW SYSTEM BY SAGICO constructs of monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking cap set screws, rods, hooks, monoaxial and multiaxial transverse connectors and associated surgical instruments. The RIPLEY SPINAL SCREW SYSTEM BY SAGICO implants are available in a variety of sizes to accommodate individual patient anatomy and pathology conditions. RIPLEY SPINAL SCREW SYSTEM BY SAGICO is 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO included in this submission demonstrates that the RIPLEY SPINAL SCREW SYSTEM BY SAGICO is substantially equivalent to predicate devices cleared by FDA for commercial distribution in the United States market. The RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO device included:

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

- Static Compression Bending Test
- Dynamic Compression Bending Test

ASTM F1798
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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO 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 RIPLEY SPINAL SCREW SYSTEM BY SAGICO has been shown to be substantially equivalent to legally marketed predicate devices with respect to its indications for use, design, function, and materials.