June 26, 2023

Sagico VA USA, LLC
James Gibson
Project Manager
2189 W.Busch Blvd
Tampa, Florida 33612

Re: K223143
Trade/Device Name: SAGICO Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, MAX
Dated: March 17, 2023
Received: March 21, 2023

Dear James 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. 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/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 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 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
Brent Showalter, Ph.D.
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)*
K223143

Device Name

SAGICO Spinal System

Indications for Use *(Describe)*

The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO are to be filled with autogenous bone graft material. The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO is intended to be used with supplemental fixation cleared by the FDA to properly utilize this device.

The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO is to be filled with autogenous bone graft material and implanted via an open anterior approach. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO must be used with the additional internal fixation (e.g. anterior plate or cervical pedicle screws) cleared by the FDA to properly utilize this device.

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
As required by section 807.92(c)

Device Trade Name(s):	The SAGICO Spinal System
Classification Panel:	Orthopedics
Class and Reference:	Class II (*21 CFR Section 890.5900*)
Product Code(s):	OVE, MAX
Classification Name(s):	Intervertebral Fusion Device with Bone Graft
Regulation Number(s):	888.3080 and 888.3060
Applicant/Official Contact Person:	James J. Gibson, Jr., PHD, CPA SAGICO Project Manager Email: JG@SAGICOUSA.com Tel. (813) 815-0613 / Fax (813) 433-5586
Submitter /Manufacturer:	SAGICO VA USA, LLC 2189 West Busch Blvd Tampa, Florida 33612 Tel. (813) 815-0613 / Fax (813) 433-5586
Preparation Date:	June 26th, 2023

Substantial Equivalence and Predicate Devices***:**

SAGICO VA USA, LLC is making the claim that The SAGICO SPINAL System is substantially equivalent to legally marketed predicate devices that are distributed for similar indications, and/or have similar design features.

The SAGICO SPINAL System is substantially equivalent with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness.

The predicates are listed below:

Legally Marketed Predicate Device	**Distributor/Manufacture Name**	**Regulatory Class and Product Code**	**510(K) Registration Number**
SAGICO IBF System	Spinal Analytics & Geometrical Implant Co, LLC	MAX, ODP, MQP	K161710

Device Description:
LUMBAR: The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO are interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO implants are provided in different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral and can expand to the desired height. The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO implants are to be filled with autogenous bone graft material. Protrusions are located on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

CERVICAL: The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO are interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO implant is intended to be used between two contiguous levels from C2 to T1 and placed via an open anterior surgical approach. The implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO implants are comprised of PEEK Optima LT1 and include large central hollow window to be filled with autogenous bone graft material. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO implants features protrusions located on the top and bottom surfaces of PEEK spacers to engage with superior and inferior endplates of the adjacent vertebrae to resist rotational and expulsion. The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO includes internal titanium spin blade offering internal fixation and expansion of 1mm in height allowing low profile insertion. The SAGICO Spinal System – Carney Expandable Cervical

Spinal Implant by SAGICO implant is intended to be used with FDA cleared supplemental fixation to properly utilize the device.

MATERIALS: The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implants, and Carney Expandable Cervical Spinal Implants by SAGICO, are implants that are manufactured from medical Grade PEEK (Polyetheretherketone) OPTIMAT LT I (InvibioTM) per ISO 10993-1 USP Class VI, and ASTM F2026, Titanium Alloy per ASTM F136 and Tantalum beads /rods to be Grade IJNS R05200, IJNS R05400 according to ASTM F560.

FUNCTION: The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implants, and Carney Expandable Cervical Spinal Implants by SAGICO implants are intervertebral body fusion devices to help restore integrity to the spine in the cervical and lumbar regions.

INDICATIONS FOR USE:

LUMBAR
The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO are to be filled with autogenous bone graft material. The SAGICO Spinal System – Lucas Expandable Lumbar Spinal Implant by SAGICO is intended to be used with supplemental fixation cleared by the FDA to properly utilize this device.

CERVICAL
The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO is to be filled with autogenous bone graft material and implanted via an open anterior approach.

The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO must be used with the additional internal fixation (e.g. anterior plate or cervical pedicle screws) cleared by the FDA to properly utilize this device.

NON-CLINICAL PERFORMANCE DATA:
Non-clinical performance data testing conducted to support substantial equivalence for The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO and the Lucas Expandable Lumbar Spinal Implant by SAGICO.

ASTM F2077
Standard Test Methods for Intervertebral Body Fusion Devices
- Static and Dynamic Compression Test
- Static and Dynamic Compression Shear Test
- Static and Dynamic Torsion Test

ASTM F2267-04
Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression

ASTM F04.25.02.02
Static Push-out Test

Conclusion: The results of this non-clinical testing demonstrate that the performance The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO and the Lucas Expandable Lumbar Spinal Implant by SAGICO are substantially equivalent to legally marketed predicate devices.

SUBSTANTIAL EQUIVALENCE CONCLUSION:
The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO and the Lucas Expandable Lumbar Spinal Implant by SAGICO implants, are similar to the predicate devices with respect to design, indication for use, performance and technical characteristics.

The information provided within this premarket notification supports substantial equivalence of The SAGICO Spinal System – Carney Expandable Cervical Spinal Implant by SAGICO and the Lucas Expandable Lumbar Spinal Implant by SAGICO implants to the cited predicate devices.