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

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

June 29, 2017

Re: K161710
Trade/Device Name: SAGICO IBF SYSTEM – ARIA LUMBAR,
SAGICO IBF SYSTEM – ARION CERVICAL
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVE
Dated: May 26, 2017
Received: May 31, 2017

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.

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" (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.

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,

Mark N. Melkerson -S

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)*
K161710

Device Name
SAGICO IBF System – ARIA LUMBAR

Indications for Use *(Describe)*

SAGICO IBF System - ARIA Lumbar implants 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).

SAGICO IBF System - ARIA Lumbar are to be filled with autogenous bone graft material. The SAGICO IBF System - ARIA Lumbar implant is intended to be used with supplemental fixation 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K161710

Device Name
SAGICO IBF System – ARION CERVICAL

Indications for Use *(Describe)*

The SAGICO IBF System – ARION Cervical implant is 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 IBF System – ARION Cervical implant is to be filled with autogenous bone graft material and placed via open anterior approach. The SAGICO IBF System – ARION Cervical implant must be used with 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.

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510(k) Summary
As required by section 807.92(c)

Device Trade Name(s): SAGICO IBF SYSTEM – ARIA LUMBAR
SAGICO IBF SYSTEM – ARION CERVICAL

Classification Panel: Orthopedics
Class and Reference: Class II (*21 CFR Section 888.3080*)
Product Code(s): MAX, OVE
Classification Name(s): Intervertebral Body Fusion Device

Regulation Number(s): 888.3080

Applicant/Official Contact Person: James J. Gibson, Jr., PhD
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Submitter /Manufacturer: Spinal Analytics & Geometrical Implant Co, LLC
dba/ SAGICO
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Tel. (813) 815-0613 / Fax (813) 433-5586

Preparation Date: June 28th, 2017

Predicate Devices:

Legally Marketed Predicate Devices	Manufacturer Name	Predicate Device	Regulatory Class and Product Code	510(K) Number
Caliber Spacer	Globus Medical, Inc	Primary	MAX	K102293
PATRIOT Lumbar Spacers	Globus Medical, Inc	Additional	MAX	K072970
LDR Spine ROI-C Cervical Cage System	LDR Spine USA	Additional	OVE	K150765
Valeo Spacer System	Amedica Corporation	Additional	OVE	K113559

These predicate devices are cleared and legally marketed, distributed for similar indications, and/or have similar design features. The SAGICO IBF Systems are substantially equivalent with respect to design, indication for use, technological characteristics, and principles of operation.

Device Description:
SAGICO IBF System - ARIA Lumbar implants are interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. SAGICO IBF System - ARIA Lumbar 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 IBF System – ARIA Lumbar implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The SAGICO IBF System - ARIA Lumbar 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.

SAGICO IBF System - ARION Cervical implants are interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. SAGICO IBF System - ARION Cervical 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. SAGICO IBF System - ARION Cervical implants are comprised of PEEK Optima LT1 and include large central hollow window to be filled with autogenous bone graft material. SAGICO IBF System - ARION Cervical 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. SAGICO IBF System - ARION Cervical includes internal titanium spin blade offering internal fixation and expansion of 1mm in height allowing low profile insertion. SAGICO IBF System - ARION Cervical implant is intended to be used with FDA cleared supplemental fixation to properly utilize the device.

The SAGICO IBF System ARIA Lumbar and ARION Cervical implants are manufactured from medical Grade PEEK (Polyetheretherketone) OPTIMAT LT I (Invibio^{TM}) 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.

The SAGICO IBF System ARIA Lumbar and ARION Cervical implants are intervertebral body fusion devices to help restore integrity to the spine in the cervical and lumbar regions.

INDICATIONS FOR USE:
SAGICO IBF System - ARIA Lumbar implants 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). SAGICO IBF System - ARIA Lumbar are to be filled with autogenous bone graft material. The SAGICO IBF System - ARIA Lumbar implant is intended to be used with supplemental fixation cleared by the FDA to properly utilize this device.

The SAGICO IBF System – ARION Cervical implant is 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 IBF System – ARION Cervical implant is to be filled with autogenous bone graft material and placed via open anterior approach. The SAGICO IBF System – ARION Cervical implant must be used with 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 IBF System – ARIA Lumbar and ARION Cervical devices included:

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 of the SAGICO IBF System – Aria Lumbar and Arion Cervical are substantially equivalent to legally marketed predicate devices.

SUBSTANTIAL EQUIVALENCE CONCLUSION:
The SAGICO IBF Systems – ARIA Lumbar and ARION Cervical 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 IBF Systems - ARIA Lumbar and ARION Cervical implants to the cited predicate devices.