November 21, 2023

Spinal Analytics & Geometrical Implant Co, LLC
James J. Gibson, Jr., Ph.D., CPA
2189 W Busch Blvd
Tampa, Florida 33612

Re: K233191
Trade/Device Name: TotalTi ACDF by SAGICO
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: September 27, 2023
Received: September 28, 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,

Brent Showalter -S

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)*
K233191

Device Name
TotalTi ACDF by SAGICO

Indications for Use *(Describe)*
The TotalTi ACDF 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 TotalTi ACDF by SAGICO is to be filled with autogenous bone graft material and implanted via an open anterior approach and deployment of the internal blades. The TotalTi ACDF by SAGICO is designed in a manner to be used with the additional 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Executive Summary

Device Trade Name(s):	TotalTi ACDF by SAGICO
Classification Panel:	Orthopedics
Class and Reference:	Class II
Product Code(s):	OVE
Classification Name(s):	Intervertebral Body Fusion Device
Regulation Number(s):	21 CFR 888.3080
Applicant/Official Contact Person:	James Gibson, PhD, CPA
Email:	JG@SAGICO.com
Submitter /Manufacturer:	Spinal Analytics & Geometrical Implant Co, LLC (dba/ SAGICO) 2189 West Busch Blvd Tampa, Florida 33612 Tel. (813) 830-3636
Preparation Date:	November 20, 2023

Purpose of Submission:
The purpose of this submission is to request new and separate clearance for the ACDF implant known as the "TotalTi ACDF by SAGICO".

PRIMARY PREDICATE AND ADDITIONAL PREDICATE DEVICES:

Legally Marketed Predicate Device	Distributor/Manufacture Name	Regulatory Class and Product Code	510(K) Registration Number
PRIMARY PREDICATE **TITUS TITANIUM CERVICAL BY SAGICO**	**SAGICO VA USA, LLC**	**OVE**	**K221138**
Additional Predicates			
SAGICO IBF System	Spinal Analytics & Geometrical Implant Co, LLC (dba/ SAGICO)	OVE	K161710
LDR Spine Cervical Interbody Fusion System	LDR Spine	OVE	K091088
TiWAVE-C Porous Titanium Cervical Cage	Kalitec Direct, LLC	OVE	K180401

DEVICE DESCRIPTION:

The TotalTi ACDF by SAGICO, is a spinal system of Interbody Fusion (IBF) devices used to provide structural stability in skeletally mature individuals following discectomy. The TotalTi ACDF by SAGICO, is intended to be used between two contiguous levels from C2 to T1 and placed via an open anterior surgical approach. The implants are customizable additively manufactured and available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The TotalTi ACDF by SAGICO, incorporates a vertical cavity (a large central hollowed window) designed to be packed with and filled with autogenous bone graft material to promote fusion. The TotalTi ACDF by SAGICO implant requires the internal fixation blades to be deployed and is designed to be used with FDA cleared supplemental fixation to properly utilize the device. The TotalTi ACDF by SAGICO implants features protrusions located on the top and bottom surfaces to engage with superior and inferior endplates of the adjacent vertebrae to resist rotational and expulsion.

MATERIALS: The TotalTi ACDF by SAGICO are additively manufactured implants from titanium alloy Ti-6Al-4V ELI. The TotalTi ACDF by SAGICO includes additively manufactured spacer, integrated fixation anchors per ASTM F3001and traditionally machined titanium alloy anchors lock per ASTM F136.

FUNCTION: The TotalTi ACDF by SAGICO implants are intervertebral body fusion devices to help restore integrity to the spine in the cervical region.

INDICATIONS FOR USE:

The TotalTi ACDF 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 TotalTi ACDF by SAGICO is to be filled with autogenous bone graft material and implanted via an open anterior approach and deployment of the internal blades. The TotalTi ACDF by SAGICO is designed in a manner to be used with the additional 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 TotalTi ACDF by SAGICO includes:

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

OTHER ADDITIONAL TESTING
Static Axial Pullout Test, Strength of Cage with Blade, Expulsion
Static Push-Out test, Strength of Deployment of Spin Blade, Effect of Anchors Deployment

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The TotalTi ACDF by SAGICO implants are similar to legally marketed and FDA 510(k) Cleared 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 TotalTi ACDF by SAGICO implants to the cited predicate devices.