August 14, 2023

Southern Medical (Pty) Ltd
℅ Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K230608
Trade/Device Name: SPICCA Stand-Alone Cervical Fusion Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: July 19, 2023
Received: July 19, 2023

Dear Nathan Wright:

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,

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.

Submission Number *(if known)*

K230608

Device Name

SPICCA Stand-Alone Cervical Fusion Cages

Indications for Use *(Describe)*

The SPICCA Stand-Alone Cervical Fusion Cages are stand-alone interbody fusion devices intended for spinal fusion procedures at one or two levels from the C2/C3 disc space to the C7/T1 disc space in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine.

Implants are to be implanted via an open, anterior approach and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices. The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

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

Submitter's Name:	Southern Medical (Pty) Ltd
Submitter's Address:	55 Regency Drive Route 21 Corporate Park Irene, Centurion, Gauteng 0178 South Africa
Submitter's Telephone:	+27 12 667 6243/4
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 3, 2023
Trade or Proprietary Name:	SPICCA Stand-Alone Cervical Fusion Cages
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The SPICCA Stand-Alone Cervical Fusion Cages are single-use, sterile, PEEK (ASTM F560) anterior cervical interbody fusion cages with integrated Ti-6Al-4V ELI (ASTM F136) screws that are intended to be implanted between two adjacent vertebral bodies as part of single or multilevel Anterior Cervical Discectomy and Fusion (ACDF) procedures. The SPICCA Stand-Alone Cervical Fusion Cages which are offered in the SPICCA-SP version and SPICCA-S2 version are offered in a variety of sizes to accommodate various patient anatomies (Note: SPICCA-SP and SPICCA-S2 differ in footprint options and endplate-contacting surface shape). The cages include Tantalum (ASTM F560) radiographic markers and are offered uncoated or coated with titanium plasma spray (ASTM F1580).

INDICATIONS FOR USE
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TECHNOLOGICAL CHARACTERISTICS
The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Principle of Operation
- Structural Support Mechanism
- Materials
- Sizes
- Indications for Use

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K153352	Vertu® Ti-Bond Cervical Interbody System	Spinal Elements, Incorporated	OVE, ODP	Primary
K211111	SureMAX-SA™ Cervical Standalone System	Additive Implants, Inc.	OVE	Additional
K212853	Cervical Stand-Alone System	Eminent Spine, LLC	OVE	Additional
K141500	Optio-C™ Anterior Cervical System	Zimmer Spine, Incorporated	KWQ, OVE	Additional

PERFORMANCE DATA

The SPICCA Stand-Alone Cervical Fusion Cages have been tested in the following test modes:

- Static & Dynamic Axial Compression per ASTM F2077
- Static & Dynamic Compression Shear per ASTM F2077
- Static & Dynamic Torsion per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the SPICCA Stand-Alone Cervical Fusion Cages are sufficient for the intended use and are substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SPICCA Stand-Alone Cervical Fusion Cages are substantially equivalent to the predicate device.