December 8, 2022

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

Re: K221182
Trade/Device Name: Southern Transforaminal Lumbar Interbody Fusion (TLIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 11, 2022
Received: November 14, 2022

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,

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)*
K221182

Device Name
Southern Transforaminal Lumbar Interbody Fusion (TLIF)

Indications for Use *(Describe)*

The Southern Transforaminal Lumbar Interbody Fusion (TLIF) family (PLIF Caliber Lordotic, TLIF Bullet, and TLIF Camber) are indicated for use as interbody fusion devices in the lumbar spine, auxiliary to supplementary lumbar spinal fixation systems, such as posterior pedicle screw and rod systems. The PLIF Caliber Lordotic devices are designed to be implanted bi-laterally following a posterior approach. The devices are intended to be used with autograft to facilitate fusion.

The devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L1 to S1. DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The devices may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Patients should have undergone at least six months of non-operative treatment.

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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K221182 - 510(K) SUMMARY

Submitter's Name:	Southern Medical (Pty) Ltd
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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:	November 10, 2022
Trade or Proprietary Name:	Southern Transforaminal Lumbar Interbody Fusion (TLIF)
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Southern Transforaminal Lumbar Interbody Fusion (TLIF) family including the PLIF Caliber Lordotic, the TLIF Bullet, and the TLIF Camber consists of implants with various widths, heights, and lengths to accommodate individual patient anatomy. The Southern TLIF family implants are offered with straight or curved profiles. The straight profiles include the PLIF Caliber Lordotic (a PLIF) implanted from the posterior approach and the TLIF Bullet (a T-PLIF or straight TLIF) implanted from the transforaminal approach. The curved version is the TLIF Camber (a curved TLIF) implanted from the transforaminal approach.

The implants are to be packed with autogenous bone graft to facilitate fusion. The devices are intended to provide mechanical support to the implanted level until biologic fusion is achieved. The Southern TLIF family implants are manufactured from PEEK per ASTM F2026 with tantalum markers per ASTM F560. The curved TLIF designs include a titanium alloy hinge (Ti-6Al-4V per ASTM F136). The Southern TLIF family implants are provided sterile.

INDICATIONS FOR USE

The Southern Transforaminal Lumbar Interbody Fusion (TLIF) family (PLIF Caliber Lordotic, TLIF Bullet, and TLIF Camber) are indicated for use as interbody fusion devices in the lumbar spine, auxiliary to supplementary lumbar spinal fixation systems, such as posterior pedicle screw and rod systems. The PLIF Caliber Lordotic devices are designed to be implanted bi-laterally following a posterior approach. The devices are intended to be used with autograft to facilitate fusion.

The devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L1 to S1. DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The devices may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Patients should have undergone at least six months of non-operative treatment.

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 the same between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Product Code**	**Predicate Type**
K150061	LUCENT®, LUCENT Ti-BOND®	Spinal Elements, Inc.	MAX	Primary
K171657, K092193	ShurFit 2C Lumbar Interbody Fusion (originally Spinal USA Intervertebral Body Fusion Device)	Precision Spine, Inc. (formerly Spinal USA)	MAX	Additional
K172341	NuVasive® Modulus TLIF Interbody System	NuVasive, Inc.	MAX, PHM	Additional
K113561	TM Ardis® Interbody System	Zimmer Trabecular Metal Technology, Inc.	MAX	Additional
K133614	Aleutian IBF System (Lumbar)	K2M, Inc.	MAX	Additional

PERFORMANCE DATA

The Southern TLIF family (PLIF Caliber Lordotic and TLIF Bullet) has been tested in the following test modes:

- Static and Dynamic Axial Compression per ASTM F2077
- Static and Dynamic Compression Shear per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Southern TLIF is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Southern TLIF family (PLIF Caliber Lordotic, TLIF Bullet, and TLIF Camber) is substantially equivalent to the predicate device.