June 13, 2023

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

Re: K231145
Trade/Device Name: Axis Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 21, 2023
Received: April 21, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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)*
K231145

Device Name
Axis Anterior Cervical Plate System

Indications for Use *(Describe)*

The Axis Anterior Cervical Plate System is intended for use in skeletally mature patients for anterior screw fixation to the cervical spine (C2-T1) as an adjunct to fusion for the treatment of the following indications: (a) degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); (b) trauma (including fractures); (c) tumours; (d) deformity (defined as kyphosis, lordosis or scoliosis); (e) spondylolisthesis; (f) spinal stenosis; (g) pseudarthrosis and (h) revision of previous surgery.

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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K231145 - 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:	April 21, 2023
Trade or Proprietary Name:	Axis Anterior Cervical Plate System
Common or Usual Name:	Anterior Cervical Plate System
Classification Name:	Appliance, Fixation, Spinal Intervertebral Body
Classification:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Axis Anterior Cervical Plate System (also called the Axis2 Anterior Cervical Fusion Plate in markets outside the US) is intended for anterior screw fixation to the cervical spine. The Axis Anterior Cervical Plate System consists of a variety of sizes of bone plates and screws to accommodate anatomical needs. The components are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The implants are provided in sterile and non-sterile packaging.

INDICATIONS FOR USE

The Axis Anterior Cervical Plate System is intended for use in skeletally mature patients for anterior screw fixation to the cervical spine (C2-T1) as an adjunct to fusion for the treatment of the following indications: (a) degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); (b) trauma (including fractures); (c) tumours; (d) deformity (defined as kyphosis, lordosis or scoliosis); (e) spondylolisthesis; (f) spinal stenosis; (g) pseudarthrosis and (h) revision of previous surgery.

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:

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

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K201979	Cervical Plate System	Eminent Spine, LLC	KWQ	Primary
K132994	Anodyne Anterior Cervical Plate System	CoreLink, LLC	KWQ	Additional

PERFORMANCE DATA

The Axis Anterior Cervical Plate System has been tested in the following test modes:

- Static & Dynamic Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717

The results of this non-clinical testing show that the strength of the Axis Anterior Cervical Plate System 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 Axis Anterior Cervical Plate System is substantially equivalent to the predicate device.