February 11, 2019

Sapphire Medical Group
Mr. Anthony Ruggiero
President
32565 B Golden Lantern Street, Suite 113
Dana Point, California 92629

Re: K183073
Trade/Device Name: SMG 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: November 27, 2018
Received: November 27, 2018

Dear Mr. Ruggiero:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183073

Device Name
SMG Anterior Cervical Plate System

Indications for Use *(Describe)*
The SMG Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:
• degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
• spondylolisthesis,
• trauma (i.e. fractures or dislocations),
• tumors,
• deformity (defined as kyphosis, lordosis, or scoliosis),
• failed previous fusion (pseudoarthrosis)
• spinal stenosis.

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

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter: Sapphire Medical Group
32565 B Golden Lantern Street
Suite 113, Dana Point, CA 92629, United States
Phone. +1-949-939-8502

Contact Person: Anthony Ruggiero

Date prepared: November 01, 2018

2. Device Identification

Trade Name	SMG Anterior Cervical Plate System
Common Name	Anterior Cervical Plate
Product Code	KWQ
Regulatory Class	Spinal Intervertebral Body Fixation Orthosis (21 CFR888.3060)
Classification Name	Class II

3. Predicate or legally marketed devices which are substantially equivalent

The design feature and indications for use for the subject SMG Anterior Cervical Plate System is exactly the same as the following predicates:

- Primary predicate device: CastleLoc-P Anterior Cervical Plate System (K143271)
- Additional predicate device: LnK Anterior Cervical Plate System (K143279)

4. Description of the Device

The SMG Anterior Cervical Plate System is composed of plates, screws and lockers which are made from titanium alloy Ti-6Al-4V ELI (ASTM F136). These plates attach to the anterior cervical spine with a minimum of four screws per plate. The plates are offered in one-level, two-level, three-level, four-level fusion configurations (13~97mm). The plate screws are 3.5mm and 4.0mm diameter head screws. They are self-tapping and self-drilling threaded. This device is provided as non-sterile.

5. Indication for use

The SMG Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- failed previous fusion (pseudoarthrosis)
- spinal stenosis.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

No	Item	Subject device	Primary Predicate device	Additional Predicate device
		SMG Anterior Cervical Plate System	CastleLoc-P Anterior Cervical Plate System	LnK Anterior Cervical Plate System
1	Manufacturer	Sapphire Medical Group (Contract manufacturer: L&K BIOMED CO., LTD.)	L&K BIOMED Co., Ltd.	L&K BIOMED Co., Ltd.
2	Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
3	510(K) Number	-	K143271	K143279
4	Product Code	KWQ	KWQ	KWQ
5	Class	Class Ⅱ	Class Ⅱ	Class Ⅱ
6	Sterility	Non-sterile	Non-sterile	Non-sterile
7	Intended Use	The SMG Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with: -degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and	The CastleLoc-P Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with: -degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),	The LnK Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with: -degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),

		radiographic studies), -spondylolisthesis, -trauma (i.e. fractures or dislocations), -tumors, -deformity (defined as kyphosis, lordosis, or scoliosis), -failed previous fusion (pseudoarthrosis) -spinal stenosis.	-spondylolisthesis, -trauma (i.e. fractures or dislocations), -tumors, -deformity (defined as kyphosis, lordosis, or scoliosis), -failed previous fusion (pseudoarthrosis) -spinal stenosis.	-spondylolisthesis, -trauma (i.e. fractures or dislocations), -tumors, -deformity (defined as kyphosis, lordosis, or scoliosis), -failed previous fusion (pseudoarthrosis) -spinal stenosis.

7. Comparison of the technology characteristics of the device to predicate and legally marketed devices

The subject device 'SMG Anterior Cervical Plate System' is exactly the same device as the predicate device(s): CastleLoc-P Anterior Cervical Plate System (K143271) and LnK Anterior Cervical Plate System (K143279). Therefore, it is substantially equivalent to these devices which are currently being marketed in terms of design, function and intended use.

8. Performance Data

Static compression bending, tension, torsion and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. These data demonstrate substantial equivalence in terms of performance bench testing.

9. Conclusion

The SMG Anterior Cervical Plate System is substantially equivalent to the devices referenced above for the intended use.