May 9, 2019

MiRus™, LLC
Mr. Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway SE, Suite 108
Marietta, Georgia 30067

Re: K190666
Trade/Device Name: CYGNUS™ 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: March 13, 2019
Received: March 15, 2019

Dear Mr. Bauman:

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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190666

Device Name
CYGNUS™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The CYGNUS™ Anterior Cervical Plate System is a spinal intervertebral body fixation orthosis which is intended to provide temporary immobilization and stabilization of the anterior spine during the development of cervical spinal fusions (C2 to C7) in patients with: (1) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); (2) Spondylolisthesis; (3) Trauma (including fractures or dislocations); (4) Spinal cord stenosis; (5) Deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis); (6) Tumors; (7) Pseudarthrosis; (8) Failed previous fusions.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

I. SUBMITTER

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II. OFFICIAL CORRESPONDENT

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III. DATE PREPARED

March 13, 2019

IV. DEVICE

Name of Device	CYGNUS™ Anterior Cervical Plate System
Common Name	Spinal Intervertebral Body Fixation Orthosis
Classification Name	21 CFR 888.3060
Regulatory Class	Class II
Product Codes	KWQ
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Primary:
Synthes CSLP System (K000742)
Additional:
EBI Anterior Cervical Plate (K001794)
Aesculap ABC Plate (K974706)
Reference:
MiRus Atlas Plating System (K190415)

VI. DEVICE DESCRIPTION

The CYGNUS™ Anterior Cervical Plate System consist of implants manufactured from Commercially Pure Titanium per ASTM F67, Titanium-15 Molybdenum per ASTM F2066, and Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136. and instrumentation manufactured from stainless steel per ASTM F899. The Anterior Cervical Plate Devices are offered in four configurations of various sizes to accommodate different patient anatomy. The implants will be provided non-sterile and are intended for single use only.

VII. INDICATIONS FOR USE

The CYGNUS™ Anterior Cervical Plate System is a spinal intervertebral body fixation orthosis which is intended to provide temporary immobilization and stabilization of the anterior spine during the development of cervical spinal fusions (C2 to C7) in patients with: (1) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); (2) Spondylolisthesis; (3) Trauma (including fractures or dislocations); (4) Spinal cord stenosis; (5) Deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis); (6) Tumors; (7)Pseudarthrosis; (8) Failed previous fusions.

VIII. PREDICATE DEVICE COMPARISON

The documentation provided shows that the CYGNUS™ Anterior Cervical Plate System is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics and labeling.

IX. PERFORMANCE DATA

Static and dynamic compression bending and static torsion were performed adhering to ASTM F1717-15. The preclinical testing listed above that was performed on the CYGNUS™ Anterior Cervical Plate System indicate that it is substantially equivalent to the predicate devices in mechanical performance.

X. CONCLUSONS

The CYGNUS™ Anterior Cervical Plate System does not raise any new questions of safety or efficacy when compared to the predicate device(s). The CYGNUS™ Anterior Cervical Plate System has demonstrated that it is substantially equivalent in mechanical performance, indications for used, intended use, technological characteristics, materials and labeling to legally marketed predicate devices.