September 16, 2022

MiRus, LLC
Jordan Bauman
Vice President, Regulatory Affairs
1755 West Oak Parkway, Suite 100
Marietta, Georgia 30062

Re: K220441
Trade/Device Name: CYGNUS™ MoRe 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: August 17, 2022
Received: August 17, 2022

Dear Jordan 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/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, 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)*

K220441

Device Name

CYGNUS™ MoRe Anterior Cervical Plate System

Indications for Use *(Describe)*

The CYGNUS™ MoRe 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 spine 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) Pseudoarthrosis; (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

August 15, 2022

IV. DEVICE

Name of Device	CYGNUS™ MoRe 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 Predicate
CYGNUS™ Anterior Cervical Plate System – MiRus, LLC (K190666)
Reference Device
ATLAS™ Plating System (K191867)

VI. DEVICE DESCRIPTION

The CYGNUS™ MoRe Anterior Cervical Plate System is a spinal intervertebral body fixation orthosis used to provide structural stability following anterior cervical discectomy and fusion for cervical degenerative disorders.

The CYGNUS™ MoRe Anterior Cervical Plate System consists of implants manufactured from Wrought Molybdenum-47.5 Rhenium Alloy (MoRe) per ASTM F3273, Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136, and instrumentation manufactured from Stainless Steel per ASTM F899. The system is offered in several configurations of various sizes to accommodate different patient anatomy and surgical approaches.

VII. INDICATIONS FOR USE

The CYGNUS™ MoRe 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 spine 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) Pseudoarthrosis; (8) Failed previous fusions.

VIII. PREDICATE DEVICE COMPARISON

The CYGNUS™ MoRe Anterior Cervical Plate System has the same technological characteristics as the predicate devices including design, intended use, function, and range of sizes. The predicate device components are manufactured from titanium alloys (ASTM F136 and F2066). The CYGNUS™ MoRe Anterior Cervical Plate System components are manufactured from titanium alloy (ASTM F136) and molybdenum-rhenium alloy (ASTM F3273), which are the same materials as the reference device.

IX. PERFORMANCE DATA

The mechanical performance profile of CYGNUS™ MoRe Anterior Cervical Plate System was assessed through static and dynamic construct testing in accordance with the following test methods:

- Static compression bending (ASTM F1717-21)
- Static torsion testing (ASTM F1717-21)
- Dynamic compression bending (ASTM F1717-21)

Bacterial endotoxin testing was performed per ANSI/AAMI ST72:2011 using the limulus amebocyte lysate (LAL) pyrogen testing.

X. CONCLUSIONS

The CYGNUS™ MoRe Anterior Cervical Plate System has the same intended use, indications for use, labeling, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials. Performance data demonstrate that the CYGNUS™ MoRe Anterior Cervical Plate System is substantially equivalent to legally marketed predicate systems.