November 18, 2022

SIGNUS Medizintechnik GmbH
Mr. Holger Noss
Head of Regulatory & Quality
Industriestrasse 2
Alzenau, Bavaria 63755
Germany

Re: K220658
Trade/Device Name: COSY Cervicothoracic Occipital Rod-Screw System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: October 24, 2022
Received: October 24, 2022

Dear Mr. Noss:

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)*
K220658

Device Name
COSY Cervicothoracic Occipital Rod-Screw System

Indications for Use *(Describe)*
The COSY Cervicothoracic Occipital Rod-Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instabilities or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The COSY cervicothoracic occipital rod-screw system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of limited duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the COSY Cervicothoracic Occipital Rod-Screw System may be connected to the components of the DIPLOMAT System or MONOPOLY System using the rod-to-rod connectors or transition rods.

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.

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

Date of Perparation

February 22, 2022

Applicant

Company:	SIGNUS Medizintechnik GmbH
Street:	Industriestrasse 2
Postcode, City:	63755 Alzenau
Country:	Germany

Contact Person

Name:	Mr. Holger Noss
Position:	Head of Quality Management
Tel:	0049 6023 9166 212
E-Mail:	h.noss@signus.com

Device Name

Trade name:	COSY Cervicothoracic Occipital Rod-Screw System
Regulation Description:	Posterior Cervical Screw System
Regulation Number:	888.3075
Product Code:	NKG, KWP
Classification:	Class II
Panel:	Orthopedic

Primary Predicate Device

Trade Name	Clearance	Claim of Equivalence for:	510(k) holder
Gibralt Spine System	K160197, cleared on June 28, 2016	Predicate Device	EXACTECH Inc. (spinal assets of EXACTECHE were acquired by ChoiceSpine in 2017)

Indications for Use

The COSY Cervicothoracic Occipital Rod-Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instabilities or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The COSY cervicothoracic occipital rod-screw system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of limited duration to permit achievement of fusion. In order to achieve additional levels of fixation, the COSY Cervicothoracic Occipital Rod-Screw System may be connected to the components of the DIPLOMAT System or MONOPOLY System using the rod-to-rod connectors or transition rods.

Device Description

The COSY Cervicothoracic Occipital Rod-Screw is a multiple component, posterior spinal fixations system which consists of solid screws, cannulated screws, standard tulips, angulated tulips, curved rods, straight rods, hybrid rods, parallel connectors, inline connectors, occipital plates, occipital bone screws, hooks, and offset connectors.

All implants, except of variations of the rods, are available in Ti-6AL-4V ELI per ASTM F136. Rods are available in Ti-6AL-4V ELI per ASTM F136 or Co-Cr28-Mo6 per ASTM F1537.

The pedicle screws consist of a tulip and a pedicle screw shaft. The shaft has a prominent thread, to provide anchorage of the screw in the pedicle section of the vertebrae. Each tulip is securely attached to the rod via a set screw.
The shafts of the pedicle screws are provided in different lengths, diameters, fully or partially threaded, and with a symmetric or asymmetric angulation to provided adaptability to the patient's anatomy. The rods can be shortened on site by the surgeon.
The occipital plate is available with four or five holes and areas to be bent for better fixation to the occipital part of the skull. The plate is fixed via bone screws and as two gliding tulips to provided anchoring of the rod. The gliding tulips are constructed similar to the tulips of the pedicle screws in the area of the rod- set screw -tulip intersection.

Comparison of Technological Characteristics with the Predicate Device

The subject device has the following in common with the primary predicate device: indications for use, intended use, general design characteristics, and materials of construction. Any differences do not result in new questions of safety or effectiveness.

Mechanical Testing

Testing was conducted according to:

- Dynamic Compression-Bending per ASTM F2706-18
- Dynamic Axial Torsion per ASTM F2706-18
- Static Axial Gripping per ASTM F1798-13
- Static Compression-Bending per ASTM F2706-18
- Static Torsion per ASTM F2706-18
- Dynamic Compression-Bending per ASTM F1717-18
- Dynamic Flexion/Extension Bending per ASTM F1798-13
- Static Compression-Bending per ASTM F1717-18
- Statix Flexion/ Extension Bending per ASTM F1798-13
- Static Axial Torsion per ASTM F1717-18

Conclusion

Through assessment of technological characteristics, indications for use, and performance data, it can be concluded that the subject COSY Cervicothoracic Occipital Rod-Screw System is substantially equivalent to the predicate device.