Coligne AG
% J.D. Webb
President
The OrthoMedix Group, Inc.
4313 W. 3800, S.
West Haven, Utah 84401

May 19, 2021

Re: K210306
Trade/Device Name: GII Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: April 14, 2021
Received: April 21, 2021

Dear J.D. Webb:

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,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210306

Device Name
GII Spinal Fixation System

Indications for Use *(Describe)*
The Coligne GII Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The GII Spinal Fixation System is intended for use in the non-cervical posterior spine, in skeletally-mature patients, as an adjunct to fusion using autograft and/or allograft, the GII Spinal Fixation System is intended for use for one or more of the following: (1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) spinal stenosis, (6) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (7) spinal tumor, and/or (8) failed previous fusion (pseudoarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Coligne GII Spinal Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma.

This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Coligne AG is hereby submitting this 510(k) Summary.

1. Date Prepared

May 18, 2021

2. Submitter [510(k) owner]

Coligne AG
Utoquai 43
8008 Zurich, SWITZERLAND
Phone: 41-43-3438000

3. Primary Contact

J.D. Webb
4313 W. 3800 S
West Haven, UT 84401
512-590-5810 Tele
e-mail: jdwebb@orthomedix.net

4. Submitted Device Information

Trade Name: ***GII Spinal Fixation System***
Common Name: pedicle screw

5. Classification Information

Classification: Class II
Classification Regulation: 21 CFR 888.3070; Thoracolumbosacral pedicle screw system
Classification Product Code: NKB
Device Panel: Orthopedic

6. Reason for Submission

The reason for the current 510(k) is to add the flexStaas pedicle screws to the GII Spinal Fixation System.

7. Legally Marketed Predicate Devices

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** manufactured by Coligne AG are substantially equivalent to the following devices currently in commercial use:

Primary Predicate Device

Device: GII-Ti-Poly-Axial Screw
Company: Coligne AG
510(k) number: K083567

Additional Predicate Devices

Device: GII Spinal Fixation System
Company: Coligne AG
510(k) number: K032604

Device: CD Horizon Spinal System
Company: Medtronic
510(k) number: K202771

8. Submitted Device Description

The ***GII Spinal Fixation System*** is a top loading polyaxial pedicle screw, which, when used with rods and cross-links, results in a multiple component, posterior spinal fixation system. All the components are available in a variety of sizes to match the patient's anatomy more closely.

9. Materials

Ti-6Al-4V ELI (ISO 5832-3)

10. Indications for Use

The Coligne GII Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The GII Spinal Fixation System is intended for use in the non-cervical posterior spine, in skeletally-mature patients, as an adjunct to fusion using autograft and/or allograft, the GII Spinal Fixation System is intended for use for one or more of the following: (1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) spinal stenosis, (6) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (7) spinal tumor, and/or (8) failed previous fusion (pseudoarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Coligne GII Spinal Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma.

This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

11. Substantial Equivalence

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** are substantially equivalent to the predicate devices in terms of intended use, design, manufacturing materials, principles of operation, and technical characteristics, and raises no new issues of safety or effectiveness.

12. Summary of the Technological Characteristics Compared to Predicate

Intended Use

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** and the predicates are intended to provide immobilization and stabilization of spinal segments in thoracic, lumbar, and sacral spine as an adjunct to fusion.

Materials

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** use the same material as the predicates.

Design

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** and the predicates are equivalent in terms of shape and function.

Dimensions

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** and the predicates are equivalent in their dimensions.

Strength

The ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** have greater or equivalent strength values compared to the predicates.

13. Non-clinical Test Summary

The following tests were performed in support of this Special 510(k):

1. Dynamic flexion-extension per ASTM F1798
2. Torsional strength of screw/screwdriver interface

The testing showed that the ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** met or exceeded acceptance criteria.

14. Clinical Test Summary

No clinical studies were performed.

15. Conclusions: Non-clinical and Clinical

Coligne AG considers the ***flexStaas pedicle screws*** of the ***GII Spinal Fixation System*** to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.