December 1, 2017

coLigne, AG
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

Re: K173148
Trade/Device Name: ACIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: September 25, 2017
Received: September 29, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173148

Device Name

ACIF

Indications for Use *(Describe)*

The ACIF system is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the cervical spine (C2-T1) to facilitate fusion in case of degenerative disc disease (DDD) defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ACIF implants are placed via an anterior approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ACIF implants are to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to surgery.

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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*5*10(k) Summary: ACIF

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	September 25, 2017
Submitted By	Robert Lange coLigne, AG Utoquai 43 CH 8008 Zurich Switzerland Telephone: +41 43 343 8000 e-mail: robert.lange@coligne.com
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 Telephone: 512-388-0199 e-mail: jdwebb@orthomedix.net
Trade Name	ACIF
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device – cervical
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	DePuy, BENGAL System (K081917)
Secondary Predicate Devices	Spinal Elements, Crystal Cervical Cage (K073351) Zimmer, BAK/C Vista Interbody Fusion (P980048 S3) LDR Spine Cervical Interbody Fusion System (K091088) Medtronic, Affinity Anterior Cervical Cage (P000028)
Reference Device	ostaPek® VBR System (K072326)
Device Description	The coLigne ACIF system are used to maintain disc space distraction in skeletally mature adults requiring anterior cervical interbody fusion (ACIF). This system includes two design configurations: ACIF oscar, and ACIF oscar dome. The implants are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of bone graft.
Materials	Polyether ketone ether ketone ketone (ASTM F1876-98) Fiber carbon filaments Gold (ASTM B562-95)

Intended Use	The coLigne ACIF system is used to maintain disc space distraction in skeletally mature adults requiring anterior cervical interbody fusion (ACIF).
Substantial Equivalence Claimed to Predicate Devices	The coLigne ACIF system is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The ACIF system is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the cervical spine (C2-T1) to facilitate fusion in case of degenerative disc disease (DDD) defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ACIF implants are placed via an anterior approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ACIF implants are to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to surgery.
Technological Characteristics	Intended Use The subject ACIF system and all the predicates have similar intended uses. Materials The subject device is composed of the same materials as the reference device. Design Features/Functions The subject ACIF system and cited predicate devices share similar basic design features and functions. Dimensions The subject ACIF system is dimensionally similar to cited predicate devices. Sterilization The subject ACIF system is provided non-sterile and cited predicate devices are sterile and non-sterile for single use only. Performance Specification Mechanical testing confirmed the ACIF system demonstrated equivalent performance to the cited predicate device under the same test conditions.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F2077 • Static and dynamic torsion per ASTM F2077 • Subsidence per ASTM F2267 The results of these evaluations indicate that the coLigne ACIFare equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	coLigne, AG considers the coLigne ACIF Cervical Cages 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