November 14, 2018

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

Re: K181963
Trade/Device Name: ostaPek Interbody Fusion Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 19, 2018
Received: October 22, 2018

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. 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,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181963

Device Name
ostaPek Interbody Fusion Cages

Indications for Use *(Describe)*
The ostaPek Interbody Fusion Cages system is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the sacrolumbar spine (L2-S1) 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. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The ostaPek Interbody Fusion Cages are placed via an anterior, posterior or lateral approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ostaPek Interbody Fusion Cages are to be used with supplemental fixation cleared by the FDA for use in the lumbar spine. Patients should have at least six months of non-operative treatment prior to surgery. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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: ostaPek Interbody Fusion Cages

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

Date Prepared	October 16, 2018
Submitted By	Coligne, AG Utoquai 43 Zurich, SWITZERLAND 8008 email: Robert.Lange@coligne.com
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	ostaPek Interbody Fusion Cages
Common Name	Intervertebral Body Fusion Device
Classification Name	Intervertebral Body Fusion Device with Bone Graft, Lumbar
Class	II
Product Code	MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Brantigan I/F Cage, DePuy Spine (P960025)
Secondary Predicate Devices	Lumbar Interbody Fusion Cage System, L&K Biomed (K110783/K151140) BAK Interbody Fusion System, Zimmer Spine (P950002)
Reference Predicate Devices	Ray Threaded Lumbar Fusion Cage, Stryker (P950019) Talos PLIF, MediTech (K090707) ACIF implants, Coligne AG (K173148) ostaPek® VBR System, Coligne AG (K072326)
Device Description	The ostaPek Interbody Fusion Cages system consists of four families of cages used with four surgical approaches: the Erriva® ELIF/TLIF Cage (Extraforaminal Lumbar Interbody Fusion/ Transforaminal Lumbar Interbody Fusion), the Gemitra® TLIF Cage, the PLIF Cage (Posterior Lumbar Interbody Fusion) and PLIF Bullet Cage, and the ALIF Cage (Anterior Lumbar Interbody Fusion). All device configurations are available in multiple sizes to adequately fit patient anatomical variations. They all have bone graft windows, ridges or teeth to resist migration, and x-ray markers.
Materials	Poly-ether-ketone-ether-ketone-ketone (PEKEKK) resin (ASTM F1876) Carbon fiber filaments Gold (ASTM B562)

Intended Use	The ostaPek Interbody Fusion Cages system is used to maintain disc space distraction and structural stability until fusion occurs in skeletally mature adults requiring lumbar interbody fusion.
Substantial Equivalence Claimed to Predicate Devices	The ostaPek Interbody Fusion Cages are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The ostaPek Interbody Fusion Cages system is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the sacro-lumbar spine (L2-S1) 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. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The ostaPek Interbody Fusion Cages are placed via an anterior, posterior or lateral approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ostaPek Interbody Fusion Cages are to be used with supplemental fixation cleared by the FDA for use in the lumbar spine. Patients should have at least six months of non-operative treatment prior to surgery. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.
Summary of the technological characteristics compared to predicate	Intended Use The ostaPek Interbody Fusion Cages and all the predicates have similar intended uses. Materials The ostaPek Interbody Fusion Cages are fabricated of the same material as the predicate device. Design Features/Functions The ostaPek Interbody Fusion Cages and cited predicate devices share similar basic design features and functions. Dimensions The ostaPek Interbody Fusion Cages system is dimensionally similar to cited predicate devices. Sterilization The ostaPek Interbody Fusion Cages system is provided non-sterile and cited predicate devices are non-sterile for single use only. Performance Specification Mechanical testing confirmed the ostaPek Interbody Fusion Cages 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 (ASTM F2077) • Subsidence (ASTM F2267) • Expulsion The results of these evaluations indicate that the ostaPek Interbody Fusion Cages system is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Coligne AG considers the ostaPek Interbody Fusion Cages 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.