February 19, 2021

SpineworxX AG
% Cassandra Petrov
Regulatory Engineer
JALEX Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K202380
Trade/Device Name: Born PT-LIF Cage HA
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 22, 2021
Received: January 25, 2021

Dear Cassandra Petrov:

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,

Brent Showalter, Ph.D.
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)*
K202380

Device Name
Born PT-LIF Cage HA

Indications for Use *(Describe)*
The Born PT-LIF Cage HA is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels of the spine from L2 to S1. These DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted in open surgery via a posterior or transforaminal approach. These devices are intended to be used with supplemental fixation which has been cleared for use in the lumbosacral spine.

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

Submitted By:	SpineworxX AG Schuppisstrasse 10 9016 St. Gallen Switzerland
Date:	July 13, 2020
Contact Person:	Cassandra Petrov, Regulatory Engineer
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Device Trade Name:	Born PT-LIF Cage HA System
Device Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	MAX
Predicate Device:	K151785- Innovasis Px HA PEEK IBF System The predicate device has never been subject to recall.
Additional Predicate:	K130699- Aleutian Spine System The additional predicate device has never been subject to recall.

Device Description:
The Born PT-LIF Cage HA is an interbody fusion device which is inserted between two lumbar or lumbosacral vertebral bodies to replace a collapsed, damaged, or unstable disc. The cage is manufactured from PEEK-OPTIMA™ HA Enhanced. The cage contains a hollow center to allow for bone graft packing, and radiopaque positioning markers. The cage is designed with a bullet nose for easier insertion and serrated contact surfaces for fixation and stability. The device is available in different lengths (25, 28, 32, 36mm), heights (7-17mm in 1mm increments), and degrees of lordosis (0, 4, 8, 12, 16°). All cages are 10mm wide. The Born PT-LIF Cage HA shall be used with autogenous bone graft and supplemental fixation. The cages are single use devices, which are sterilized via gamma radiation and provided to the user in sterile packages. The instruments used to insert the cage are manufactured from medical grade stainless steel and must be sterilized prior to use.

Intended Use:
The Born PT-LIF Cage HA is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels of the spine from L2 to S1. These DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted in open surgery via a posterior or transforaminal approach. These devices are intended to be used with supplemental fixation which has been cleared for use in the lumbosacral spine.

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Summary of Technological Characteristics:

Table 1. Technological Characteristics Comparison

Item	SpineworxX AG PT-LIF Cage	Innovasis Px PEEK IBF	Aleutian (Additional)	Equivalence
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar	Intervertebral Fusion Device With Bone Graft, Lumbar	Intervertebral Fusion Device With Bone Graft, Lumbar	Equivalent
Regulation	888.3080	888.3080	888.3080	Equivalent
Common Name	Intervertebral body fusion device	Intervertebral body fusion device	Intervertebral body fusion device	Equivalent
Product Code	MAX	MAX	MAX	Equivalent
Intended Use	The Born PT-LIF Cage HA is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels of the spine from L2 to S1. These DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be	The Innovasis Px HA™ PEEK IBF System is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at	Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. Aleutian implants are intended to be used with supplemental internal fixation.	Equivalent

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	implanted in open surgery via a posterior or transforaminal approach. These devices are intended to be used with supplemental fixation which has been cleared for use in the lumbosacral spine.	the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior (PLIF) or modified transforaminal (T-PLIF) approach. This device is intended to be used in pairs and with internal supplemental spinal fixation systems such as the Innovasis Excella® Spinal System. The interior of the Px HA implant is intended to be packed with autograft.		
Description	The Born PT-LIF Cage HA is an interbody fusion device which is inserted between two lumbar or lumbosacral vertebral bodies to replace a collapsed, damaged, or unstable disc. The cage is manufactured from PEEK-OPTIMA™ HA Enhanced. The cage contains a hollow center to allow for bone graft packing, and radiopaque	The Innovasis Px HATM PEEK IBF is designed for use in a posterior (PLIF) approach to the lumbar spine. Implants are manufactured by Innovasis from Invibio® PEEK-OPTIMA® HA Enhanced*. Hydroxyapatite (HA) is fully integrated into the PEEKOPTIMA. The device is radiolucent allowing straightforward assessment of the fusion process,	The Aleutian spinal system consists of a hollow tube or horseshoe shaped structures manufactured from medical grade PEEK (polyetheretherketone). The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body endplates. The implants are manufactured from PEEK Optima LT1 per	Equivalent

	positioning markers. The cage is designed with a bullet nose for easier insertion and serrated contact surfaces for fixation and stability. The device is available in different lengths heights, and degrees of lordosis. The Born PT-LIF Cage HA shall be used with autogenous bone graft and supplemental fixation. The cages are single use devices, which are sterilized via gamma radiation and provided to the user in sterile packages. The instruments used to insert the cage are manufactured from medical grade stainless steel and must be sterilized prior to use.	while tantalum spheres are located around the periphery of the device to allow implant visualization during and after surgery. The single use implant devices feature an open cavity in the interior geometry to accommodate bone graft and maximize bone in-growth, with anti-migration teeth to engage the vertebral endplates and prevent expulsion. The implants have a slightly convex profile and are offered in a variety of different sizes to fit the anatomical needs of a wide variety of patients. The implant has a tapered leading edge which aids in implant insertion due to limited anatomical space. Reusable instruments to support the PLIF surgery are provided with the implants in custom sterilization trays.	ASTM 2026. Tantalum beads/rods are made of Grade UNS R05200, UNS R05400 according to ASTM F560. The system functions as an intervertebral body fusion device to provide support and stabilization of the lumbar segments of the spine.	
Sizes	Heights: 8-17 in 1mm increments	Heights: 8-16mm in 1mm increments	Heights: 4-12mm in 1mm increments Lengths: 24, 28mm	Equivalent-largest SpineworxX

	Lengths: 25, 28, 32, 36mm Width: 10mm Lordosis: 0, 4, 8, 12, 16°	Lengths: 22, 28, 32mm Widths: 8,10,12mm Lordosis: 0°, 5°	Width: 8.5mm Lordosis: 6,12,18°	size demonstrated equivalence in mechanical testing
Graft Window	Yes	Yes	Yes	Equivalent
Anti-Migration Features	Yes	Yes	Yes	Equivalent
Use with Supplemental Fixation	Yes	Yes	Yes	Equivalent
Material	PEEK-OPTIMA™ HA Enhanced, Tantalum	PEEK-OPTIMA™ HA Enhanced, Tantalum	PEEK-OPTIMA LT1, Tantalum	Equivalent
Mechanical Testing	Performance testing per ASTM F2077-11 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Subsidence, Expulsion	Performance testing per ASTM F2077-11 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Subsidence and Expulsion	Performance testing per ASTM F2077 for static compression, static torsion and dynamic compression.	Equivalent

Non-clinical Testing:

Mechanical:
The following mechanical tests were conducted on the largest (17mm height) cages:

- Dynamic Axial Compression per ASTM F2077 (also conducted on 8mm height)
- Dynamic Compression Shear per ASTM F2077
- Static Axial Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Static Subsidence per ASTM F2267-04
- Expulsion

The results of each of the above tests met their respective acceptance criteria and further support the substantial equivalence of the device. Further details on the mechanical testing of this device are provided within this submission.

Material Stability:
The PEEK-OPTIMA™ HA Enhanced material was tested by the material supplier for thermal transitions, estimated crystallinity, chemical composition by FTIR, density, cytotoxicity, extractables and leachables to ascertain the biological safety of the device. Testing demonstrated that sterilization and aging did not

have a significant effect on the material. Further information on stability testing is provided within this submission.

Packaging Validation:
A packaging validation was conducted on the implant pouch after shipping and handling conditioning and sterilization. Visual inspection, peel strength and dye leak testing were performed on the packages. All test samples met the acceptance criteria demonstrating that the package adequately maintains the sterility of the device.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.