FBC Device ApS
Finn Christensen, M.D., Ph.D.
CEO
Viengevej 100
Risskov, 8240 Dk

July 12, 2018

Re: K180695
Trade/Device Name: FBC 921™ (ALIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: June 7, 2018
Received: June 8, 2018

Dear Dr. Christensen:

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 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,

Melissa Hall -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)*
K180695

Device Name
FBC 921™ (ALIF)

Indications for Use *(Describe)*
The FBC 921™ is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s) and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is intended to be used with posterior supplemental spinal fixation systems that have 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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Traditional 510k
FBC 921™ (ALIF)

fbc device®

510(k) SUMMARY

Submitted by	FBC Device Aps Viengevej 100 DK-8240 Risskov DENMARK
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Date Prepared	July 11, 2018
Common Name	Intervertebral body fusion device
Trade Name	FBC 921™ (ALIF)
Classification Name	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Class	II
Product Code	OVD
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Lanx Fusion System manufactured by Lanx, LLC (K102738) Additional predicates: Lanx Fusion System manufactured by Lanx, LLC (K123767); Infix Anterior Lumbar System manufactured by Zimmer Spine, INC (K132790); 4WEB Spinal Implant Products manufactured by 4WEB, INC (K112316, K142112); Alif Interfixated System manufactured by Nuvasive, INC (K151214); Synfix Evolution Secured Spacer System manufactured by Synthes (USA) (K150673) Reference Device: Pyramid Anterior Plate Fixation System manufactured by Medtronic Sofamor Danek, INC (K013665)
Indications for use	The FBC 921™ is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD “) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s) and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is intended to be used with posterior supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Description of the device	The FBC 921™ is a two-part ALIF device consisting of top and bottom components with an integral anterior plate to allow additional fixation. Both the bottom and the top components come in three footprints. The top component comes in three footprints and one size. It has a starting lordosis of 9 degrees. Lordosis for each assembly is adjustable between 9 and 21 degrees. The bottom component includes the height variation. It comes in the three footprints and four heights (8, 10, 12, and 14mm). The device is anchored to the superior and inferior vertebra using three Ø5.5 variable angle screws. The top and bottom components are made of titanium alloy (Ti-6Al-4V) additively manufactured from biocompatible titanium alloy (Ti-6Al-4V) using powder per ASTM F3001 which are then machined to their final geometry. Screws are made from an implant grade titanium alloy (Ti6Al4V ELI) meeting the requirements of ASTM F136. The FBC 921™ is a single-use device delivered sterile (gamma sterilization) and supplied with surgical instruments (reusable – provided non-sterile).
Technological characteristics compared to the predicate devices	As was established in this submission, the FBC 921™ is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. FBC 921™ was shown to be substantially equivalent and have the same or similar technological characteristics to its predicate devices through comparison in areas including intended use, indications for use, function, material composition and manufacturing process, design, range of sizes and mechanical performance.
Non-clinical performance data	Nonclinical testing was performed to demonstrate that the FBC 921™ is substantially equivalent to other predicate devices. The characterization of the chemical composition, mechanical and metallographic properties was performed in accordance with ASTM F2924-14 and ASTM E8/E8M. Mechanical testing in compliance with: FDA's "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the FBC 921™. The following mechanical tests were performed: Static and dynamic axial compression (per ASTM F2077), Static and dynamic shear compression (per ASTM F2077), Static torsion (per ASTM F2077), subsidence (per ASTM F2267) and expulsion (per internal protocol). The characteristics of any particulate wear debris (per ASTM F1877) generated during the mechanical test were carried out using SEM/EDS (scanning electron microscopy/energy dispersive spectrometry) techniques. Microscopic analysis was conducted of parts following dynamic testing to assess contact at all three intended areas of contact: (1) on the front of the column with the locking screw, (2) on the back of the column with the top, and (3) posteriorly. A pressure film study was conducted to evaluate contact between the top and bottom components at different lordotic angles. Lastly, assessment of the potential for locking screw loosening was conducted. In addition, dynamic testing in torsion (axial rotation) was performed to +/- 4Nm for 1 million cycles. The result of these studies shows that the FBC 921™ meets or exceeds the performance of the predicate devices and does not introduce any new risks. Therefore, the FBC 921™ is substantially equivalent to the predicate devices. Bacterial endotoxin testing per USP 39 NF 34 (2016) for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the FBC 921™ has demonstrated substantial equivalence to the identified predicate devices.