Signature Orthopaedics Pty Ltd.
Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, AU 2066 NSW

Re: K172019
Trade/Device Name: Brisbane ALIF Device, Gladstone ALIF Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: October 27, 2017
Received: October 30, 2017

Dear Dr. Brazil:

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
Indications for Use

The Signature Orthopaedics Brisbane ALIF and Gladstone ALIF systems are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I 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 nonoperative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach. The Brisbane and Gladstone ALIF systems may be used as stand-alone devices or in conjunction with supplemental fixation. When used as a stand-alone device the subject devices must be used with all three screws.

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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2 510(K) SUMMARY

**Manufacturer:** Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia

**Device Trade Name:**
Brisbane ALIF Device
Gladstone ALIF Device

**Common Name:**
Lumbar Intervertebral Fusion Device

**Contact:**
Dr. Declan Brazil
Managing Director of Signature Orthopaedics

**Prepared By:**
Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia
Phone: +61 (2) 9428 5181
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**Date Prepared:**
June 29th, 2017

**Classification:**
Class II per 21 CFR 888.3080: Intervertebral Body Fusion Device (OVD)

**Predicate Devices:**
**Primary Predicate:**
Spine MIDLINE II-Ti™ (K141942)

**Additional Predicates:**
Benvenue Medical Inc Luna 360 Interbody System (K142023)
K2M Chesapeake Spinal System (K133494)
Spineart DYNAMIK Lumbar Interbody Device (K081888)

**Reference Predicate:**
Signature Orthopaedics NOOSA Anterior Lumbar Plate Screw (K163625)

**Device Description:**
The Signature Orthopaedics Brisbane ALIF and Gladstone ALIF cages are manufactured from PEEK-OPTIMA LT1 per ASTM-F2026. The Screws for Brisbane and Gladstone ALIF cages are manufactured from Ti6Al4V alloy per ISO 5832-3 and ASTM-F136.
The Brisbane and Gladstone ALIF cages consist of a wedge-shaped geometry and intended for implantation by an anterior approach. The centre of the cages are hollow to allow loading of bone graft. The cages are wedge shaped to restore lordosis of the fused vertebral bodies. The superior and inferior surfaces have serrated teeth to resist expulsion. The cages have three holes each on their anterior faces to facilitate the use of titanium bone screws. The use of the bone screws make the subject cages stand-alone cages. The superior and inferior
surfaces of Brisbane ALIF cage is Titanium Plasma Spray (TPS) coated per ASTM-F1580.

Indications for Use
The Signature Orthopaedics Brisbane ALIF and Gladstone ALIF systems are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I 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. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach. The Brisbane and Gladstone ALIF systems may be used as stand-alone devices or in conjunction with supplemental fixation. When used as a stand-alone device the subject devices must be used with all three screws.

Performance Testing:
Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Brisbane ALIF and Gladstone ALIF cages are adequate for anticipated in-vivo use. Non-clinical testings carried out on the worst case of the two systems as identified Finite Element Analysis (FEA) were:

- Static and dynamic compression and compression shear testing per ASTM-F2077
- Subsidence testing ASTM-F2267
- Screw insertion testing per ASTM-F543
- Screw pull-out testing per ASTM-F543
- Screw torque to failure testing per ASTM-F543

Also the coating on the Brisbane ALIF cage has undergone the following testings:

- Powder Chemistry per ASTM-F1580
- Coating Chemistry per ASTM-F1580
- Coating Thickness per ASTM-F1854-09
- Percent Porosity per ASTM-F1854-09
- Coating Roughness per ASTM-F854-09
- Static Shear per ASTM-F1044-05
- Static Tensile per ASTM-F1147-05
- Shear Fatigue per ASTM-F1160-05
- Abrasion per ASTM-F1978-00

Substantial Equivalence:
The Brisbane and Gladstone ALIF cages have the same intended use, indication for use, materials and similar design as the Centinel Spine MIDLINE II-Ti™ (K141942), K2M Chesapeake Spinal System (K133494), Spineart DYNAMIK Lumbar Interbody Device (K081888), Benvenue Medical Inc Luna 360 Interbody System (K142023) and Signature Orthopaedics NOOSA Anterior Lumbar Plate Screw (K163625). Non-clinical testing results support the substantial equivalence decision. The subject devices are expected to perform adequately during clinical use.

Conclusion:
Technical comparison of the subject and predicate devices demonstrates substantial equivalence in device design, intended use, indications for use and material. Non-clinical data support the substantial equivalence of the device.