August 18, 2020

Orion Biotech Inc.
Tun-Ling Li Chen
Official Correspondent
5F-1, No.88, Sec.2, Chong-qing N. Rd., Datong Dist.
Taipei, 103 Taiwan

Re: K190600
Trade/Device Name: "ORION" Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 20, 2020
Received: July 20, 2020

Dear Tun-Ling Li Chen:

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,

for Colin O'Neill, M.B.E.
Acting 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)*
K190600

Device Name
"ORION" Spinal System

Indications for Use *(Describe)*

The "ORION" Spinal System is a non-cervical, pedicle screw system intended to provide posterior, non-cervical immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine : degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal stenosis; tumor; pseudarthrosis and/or failed previous fusion.

In addition, the "ORION" Spinal System is also indicated for the treatment of the skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra, having fusion by autogenous bone graft, with implant fixed or attached to the lumbar and sacral spine (L3 to Sacrum), and for whom the implants is intended to be removed after solid fusion is achieved.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.

Preparation Date: July 20, 2020

Applicant/Sponsor: Orion Biotech Inc.
5F-1, No.88, Sec.2, Chong-qing N. Rd., Datong Dist.,
Taipei 103, Taiwan

Contact Person: Tung-Ling Li Chen
TEL: +886 2 2550 3366 ext. 101
Fax : +886 2 2559 3366
Email: tunglingli@orionspine.com

Proprietary Name: "ORION" Spinal System

Common Name: Pedicle Screw System

Classification Name: 21 CFR 888.3070
Thoracolumbosacral Pedicle Screw System

Classification Identification: Class II

Product Codes: NKB

Predicate Device: Facilis Spinal System K161231

Device Description:
The "ORION" Spinal System is a system that is intended to be used for posterior thoracolumbar fusion procedures. The system is manufactured from Ti-6Al-4V which complies with ASTM F136 and PEEK which complies with ASTM F2026. The components, which are included as part of the system, include screws, rods, links, and accessory connection components.

Indications for Use:

- The “ORION” Spinal System is a non-cervical, pedicle screw system intended to provide posterior, non-cervical immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine : degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal stenosis; tumor; pseudarthrosis and/or failed previous fusion.

- In addition, the “ORION” Spinal System is also indicated for the treatment of the skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra, having fusion by autogenous bone graft, with implant fixed or attached to the lumbar and sacral spine (L3 to Sacrum), and for whom the implants is intended to be removed after solid fusion is achieved.

Technological Characteristics

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any different issues of safety and effectiveness. The following characteristics are the same between the subject and predicates: Indications for use, Principles of operation, Materials of manufacture, Implant sizes, and Surgical technique.

Performance Data

The "ORION" Spinal System has been testing in the following test modes:
- Axial Grip per ASTM F1798
- Torsional Grip per ASTM F1798
- Static Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Dynamic Compression Bending per ASTM F1717

Conclusion

The information provided in this submission demonstrate that the subject device is substantially equivalent to the predicate device.