December 22, 2020

Prism Surgical Designs Pty Ltd
℅ Nathan Wright, M.S.
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K202820
Trade/Device Name: Australis® Anterior Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 23, 2020
Received: October 28, 2020

Dear Mr. Wright:

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 L. 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 on last page.

510(k) Number *(if known)*
K202820

Device Name
Australis® Anterior Lumbar Cage System

Indications for Use *(Describe)*

The Australis Spinal System is indicated for use as lumbar intervertebral body fusion devices for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The Australis Spinal System is intended to be used with autograft and/or allograft bone graft material comprised of cancellous and/or corticocancellous bone graft. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Australis ALIF cage. The Australis Spinal System is indended for use with supplemental fixation, such as the Prism Surgical Aurora® Anterior Lumbar Plate System.

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.

510(K) SUMMARY

Submitter's Name:	Prism Surgical Designs Pty Ltd
Submitter's Address:	15/43 Lang Parade Milton, Queensland 4064 Australia
Submitter's Telephone:	+61 7 3720 8882
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	September 23, 2020
Trade or Proprietary Name:	Australis® Anterior Lumbar Cage System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Prism Surgical Designs Australis® Anterior Lumbar Interbody Fusion (ALIF) Cage System (also referred to as Australis® Spine System and Australis® Spinal System) implants are intended to replace lumbar interbody discs and to fuse adjacent vertebral bodies following anterior lumbar discectomy stabilization and/or alignment of the lumbar spine. The Australis® ALIF cage is designed to be implanted via an anterior approach to the spine. The devices consist of wedge-shaped geometry to restore lordosis of the fused vertebral bodies and serrated teeth with three titanium pins on the inferior and superior surfaces to resist expulsion The center of the device is hollow to accept autograft and/or allograft bone graft material comprised of cancellous and/or corticocancellous bone graft to promote arthrodesis. The Australis® ALIF Cage System is to be used in conjunction with supplemental fixation.

The Australis® ALIF is offered in a variety of footprints and heights to accommodate the anatomical needs of patients. The Australis® ALIF is manufactured from PEEK per ASTM F2026 with titanium pins per ASTM F136 and ISO 5832-3 and tantalum marker beads per ASTM F560 and ISO 13782.

INDICATIONS FOR USE

The Australis Spinal System is indicated for use as lumbar intervertebral body fusion devices for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The Australis Spinal System is intended to be used with autograft and/or allograft bone graft material comprised of cancellous and/or corticocancellous bone graft. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Australis ALIF

cage. The Australis Spinal System is intended for use with supplemental fixation, such as the Prism Surgical Aurora® Anterior Lumbar Plate System.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Technological Characteristics
- Materials of manufacture
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K122639	SynCage Evolution Spacer	DePuy Synthes Spine	Primary
K172349	InFill® Interbody Fusion Device	Pinnacle Spine Group, LLC	Additional
K200541	Hive™ Stand-alone Anterior Lumbar Interbody System	HD LifeSciences LLC	Additional
K183705	IndentiTi Porous Ti Interbody System	Alphatec Spine, Inc.	Additional
K200352	Axis Spine Technologies ALIF	Axis Spine Technologies Ltd	Additional

PERFORMANCE DATA

The Australis® Anterior Lumbar Cage has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compression shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compression shear per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Australis® Anterior Lumbar Cage is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Australis® Anterior Lumbar Cage System is substantially equivalent to the predicate device.