August 5, 2020

Prism Surgical Design Pty Ltd.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K201079
Trade/Device Name: Aurora® Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 9, 2020
Received: July 10, 2020

Dear Nathan 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,

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 on last page.*

510(k) Number *(if known)*
K201079

Device Name
Aurora® Anterior Lumbar Plate System

Indications for Use *(Describe)*

The Aurora® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. The AURORA® Anterior Lumbar Plate System is indicated for in the treatment of lumbar and lumbosacral (L1-S1) spinal instability as a result of the following;

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar 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.**

# 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Prism Surgical Designs Pty Ltd |
| Submitter's Address: | 15/43 Lang Parade<br>Milton, Queensland 4064 Australia |
| Submitter's Telephone: | +61 7 3720 8882 |
| Contact Person: | Nathan Wright MS<br>Empirical Testing Corp.<br>719-351-0248<br>nwright@empiricaltech.com |
| Date Summary was Prepared: | April 21, 2020 |
| Trade or Proprietary Name: | Aurora® Anterior Lumbar Plate System |
| Common or Usual Name: | Spinal Intervertebral body Fixation Orthosis |
| Classification: | Class II per 21 CFR §888.3060 |
| Product Code: | KWQ |
| Classification Panel: | Orthopedic and Rehabilitation Devices |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Aurora® Anterior Lumbar Plate System consists of an assortment of plates and screws. Implant components are available in a variety of sizes to suit the individual patient anatomies. The Aurora® Anterior Lumbar Plate System implants are manufactured from medical grade titanium alloy Ti-6Al-4V per ASTM F136/ISO 5832-3. The Aurora® Anterior Lumbar Plate System also contains Class I manual surgical instruments and cases that are considered exempt from premarket notification.

## INDICATIONS FOR USE

The Aurora® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. The AURORA® Anterior Lumbar Plate System is indicated for in the treatment of lumbar and lumbosacral (L1-S1) spinal instability as a result of the following;

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

## TECHNOLOGICAL CHARACTERISTICS

The Aurora® Anterior Lumbar Plate System is comprised of multiple sizes of plates and screws that are inserted the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. The system is designed to provide additional support during fusion. 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 identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

| **510k Number** | **Trade or Proprietary or Model Name** | **Manufacturer** | **Predicate Type** |
|---|---|---|---|
| K052546 | AEGIS Anterior Lumbar Plate System | DePuy Spine, Inc. | Primary |
| K080429 | Pyramid® Anterior Lumbar Plate System | Medtronic Sofamor Danek, Inc. | Additional |

## PERFORMANCE DATA

The Aurora® Anterior Lumbar Plate System has been tested in the following test modes:

- Static compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Torsional properties per ASTM F543
- Driving torque per ASTM F543
- Pullout strength per ASTM F543

The results of this non-clinical testing show that the strength of the Aurora® Anterior Lumbar Plate System 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 Aurora® Anterior Lumbar Plate System is substantially equivalent to the predicate device.