



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

August 11, 2017

Re: K163625

Trade/Device Name: NOOSA Anterior Lumbar Plate System  
NAMBUCCA Anterior Lumbar Plate System  
CAIRNS 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 3, 2017

Received: July 14, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

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

510(k) Number (if known)

K163625

Device Name

NOOSA Anterior Lumbar Plate System

NAMBUCCA Anterior Lumbar Plate System

CAIRNS Anterior Lumbar Plate System

Indications for Use (Describe)

The Signature Orthopaedics NOOSA, NAMBUCCA, and CAIRNS Anterior Lumbar Plate Systems are 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. The devices are intended as temporary fixation devices until fusion is achieved. The subject systems are indicated in the treatment of lumbar or lumbosacral (L1-S1) fixation for the following indications: degenerative disc disease (DDD)(as define by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.

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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## 510(K) SUMMARY

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

**Device Trade Name:** NOOSA Anterior Lumbar Plate System  
NAMBUCCA Anterior Lumbar Plate System  
CAIRNS Anterior Lumbar Plate System

**Common Name:** Spinal Intervertebral Body Fixation Orthosis

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

**Prepared By:** Signature Orthopaedics Pty Ltd  
7 Sirius Road  
Lane Cove, NSW 2066  
Australia  
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**Date Prepared:** August 11<sup>th</sup>, 2017

**Classification:** Class II per 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis (KWQ)

**Predicate Devices:** **Primary Predicate**

- DePuy Spine AEGIS (K052546)

**Additional Predicate**

- Medtronic Sofamor Danek PYRAMID™ (K013665)
- Synthes Spine Anterior Tension Band (ATB) (K022791)

**Reference Predicate**

- Signature Orthopaedics Logical Bone Screw (K121297)

### Device Description:

The Signature Orthopaedics' NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plate Systems' components are manufactured from Ti6Al4V alloy per ISO 5832-3 and ASTM-F136.

The NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plate Systems are temporary supplemental fixation devices consisting of variety of shapes and sizes of plates and screws. The subject systems are used as an implant for the correction and stabilisation of the lumbosacral spine. The systems provide temporary stabilisation and augments the development of a solid fusion. Additionally, the subject systems can be used in conjunction with interbody fusion devices with anterior plate fixation. The subject plates are low profile and anatomically designed to provide optimal fit from anterior, lateral or

anterolateral approach. The NOOSA and NAMBUCCA systems feature anti-angulation locking cams to help restrict the angular movement of the screw within the screw holes of the plates.

**Indications for Use:**

The Signature Orthopaedics NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plate Systems are 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. The devices are intended as a temporary fixation devices until fusion is achieved. The subject systems are indicated in the treatment of lumbar or lumbosacral (L1-S1) fixation for the following indications: degenerative disc disease (DDD)(as define by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis, trauma (i.e. fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

**Performance Testing:**

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plates Systems are adequate for anticipated in-vivo use. The following non-clinical testings were carried out on the worst case sizes of the plates and screws:

- Static and dynamic compression bending testing
- Static torsion testing
- Screw insertion testing
- Screw pull-out testing
- Screw torque to failure testing

**Substantial Equivalence:**

That Signature Orthopaedics' NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plate Systems have the same intended use, indication for use, materials and similar design features as the DePuy Spine AEGIS (K052546), Medtronic Sofamor Danek PYRAMID™ (K013665), Synthes Spine ATB (K022791) Anterior Lumbar Plate Systems and Signature Orthopaedics Logical Bone Screw (K121297). Non-clinical testing results support the substantial equivalence to the predicate devices.

**Comparison of technological characteristics**

Temporary immobilisation and stabilisation of spinal segments as supplemental fixation in spinal fusion procedure is the technological principle for both the subject devices and the predicate devices. The subject and predicate devices are based on the following same technological elements:

- The indication for use of the subject devices is the same as one or more of the predicate devices
- The intended surgery sites of the subject devices matches the intended surgery sites of at least one of the predicates
- The subject devices are manufactured from the same material as two of the

predicates

- The locking mechanism on NOOSA and NAMBUCCA are identical to primary predicate
- The profile thickness of the subject devices are within the profile thickness of the predicates
- The size range of the subject devices fall within the size range of the predicates
- The subject devices accommodate the same number of supplemental screws as two of the predicates
- Both subject devices and predicates are contoured to match the vertebral body
- Both subject devices and predicates are implanted manually and the screws are hand tightened

The following technological differences exist between the subject and predicate devices:

- Some of the design features are different between the subject and predicate devices
- The material used on one of the predicates are slightly different than the subject devices
- The screw locking mechanism on two of the predicates are different the subject devices
- The indicated surgery location of two of the predicates are limited compared to the subject devices