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

Re: K230655
Trade/Device Name: PEEK RCI Screw; Bio-Composite Screw; SignaLoc Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 21, 2023
Received: March 9, 2023

Dear Mr. 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. 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,

Yu-chieh Chiu -S

Digitally signed by Yu-chieh Chiu -S
Date: 2023.05.03 16:29:42 -04'00'

Yu-Chieh Chiu, Ph.D.
Acting Assistant Director
DHT6C: Division of Stereotaxic, Trauma and Restorative 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230655

Device Name
PEEK RCI, Bio-Composite and SignaLoc Screw

Indications for Use *(Describe)*
The Signature Orthopaedics PEEK RCI, Bio-Composite and SignaLoc Screws are RCI screws intended for use in fixation of soft tissue including ligament or tendon to bone for cruciate ligament reconstruction surgeries of the knee. The screws are also intended for use in the following procedures:

- ACL repairs
- PCL repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquus advancement
- Illiotibial band tenodesis

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

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia Signature Orthopaedics Europe Ltd Unit A, IDA Business & Technology Park Garrycastle Athlone Westmeath N37 DY26 Ireland
510(k) Number	K230655
Device Trade Name:	PEEK RCI, Bio-Composite and SignaLoc Screws
Common Name:	Fastener, Fixation, Non-degradable, Soft Tissue
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 Fax: +61 (2) 8456 6065
Date Prepared:	Tuesday, May 2, 2023
Classification:	Screw, Fixation, Bone (HWC, 21 CFR 888.3040) Fastener, Fixation, Nondegradable, Soft Tissue (MBI, 21 CFR 888.3040)
Predicate Devices:	Primary Predicate Device • Smith & Nephew Biosure PK Interference Screw (K083635) Predicate Devices • Smith & Nephew BioRCI Screw (K032224) • Valeris Medical Apollo Suture Anchor System and Titan Screws (K142230) Reference Devices • Innovasis, Inc Px HA PEEK IBF System (K151785)

Device Description:

The PEEK RCI, Bio-Composite and SignaLoc Screws are interference screws which provide compression of the graft or tendon to the bony wall for biological fixation of the ligament, tendon or soft tissue to bone. The screws feature an internal cannulation to accept a guide wire and have the same drive feature. The screws have an external variable thread along the length

of the tapered shape and a rounded head. Each screw is provided individually packaged sterile for single use. The PEEK RCI is manufactured from unreinforced PEEK and the SignaLoc and Bio-Composite is manufactured from a PEEK/Hydroxyapatite composite.

Indications for Use:
The Signature Orthopaedics PEEK RCI, Bio-Composite and SignaLoc Screws are RCI screws intended for use in fixation of soft tissue including ligament or tendon to bone for cruciate ligament reconstruction surgeries of the knee. The screws are also intended for use in the following procedures:

- ACL repairs
- PCL repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus Medialis obliquus repairs
- Illiotibial band tenodesis

Summary of Technological Characteristics:
The PEEK RCI, Bio-Composite and Signaloc Screws share the following technological characteristics as the predicate devices:

- The PEEK RCI, Bio-Composite and Signaloc Screws have the same intended use as the primary and secondary predicate devices.
- The PEEK RCI, Bio-Composite and Signaloc Screws have the same indications for use as the Smith & Nephew Biosure PK Interference Screw.
- The PEEK RCI Screws are manufactured from the same material as the Smith & Nephew Biosure PK Interference Screw and the Valeris Medical Apollo Suture Anchor System and Titan Screws. The Bio-Compoiste and Signaloc Screws are manufactured from the same material as the Innovasis Px HA PEEK IBF System.
- The PEEK RCI, Bio-Composite and SignaLoc Screws have the same internal cannulation for a guide wire as the primary and secondary predicate devices.
- The PEEK RCI, Bio-Composite and SignaLoc Screws share the same drive feature as the Biosure PK Interference Screw.
- The PEEK RCI, Bio-Composite and Signaloc and the Smith & Nephew Biosure PK Interference Screw and the Smith & Nephew BioRCI Screw have a hemispherical head and are tapered.
- The PEEK RCI, Bio-Composite and Signaloc Screws are sterilised by the same method as the Smith & Nephew BioRCI Screw.

The following are the technological differences between the PEEK RCI, Bio-Composite and Signaloc Screws, and the predicate devices:

- The PEEK RCI, Bio-Composite and Signaloc Screws are sterilised by a different method to the Smith & Nephew Biosure PK Interference Screw.
- The Bio-Composite and Signaloc Screws is manufactured from a PEEK and hydroxyapatite composite where the Smith & Nephew Biosure PK Interference Screw is manufactured from only PEEK.
- The PEEK RCI, Bio-Composite and Signaloc Screws are indicated for ACL/PCL repair, where the Valeris Medical Titan Mini Inteference Screw is not, all other indications are shared by the devices.

- The Innovasis Px HA PEEK IBF System is a Posterior Lumbar Interbody Fusion (PLIF) device not an Interference Screw, but is a permanent tissue/bone contacting device of a similar length range and identical material as the Bio-Composite and Signaloc Screws.

Performance Data:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the PEEK RCI, Bio-Composite and Signaloc Screws are adequate for anticipated in-vivo use. No animal or clinical testing was required to support substantial equivalence. Non-clinical testing carried out included:

- Insertion Torque Testing per ASTM F543
- Torque to Failure Testing per ASTM F543
- Pullout Testing per ASTM F543
- Biocompatibility Evaluation per ISO 10993-1
- Pyrogenicity and Endotoxin Testing per AAMI ST72
- Packaging and Shelf-Life Testing per ASTM F1980
- Sterilization Validation per AAMI TIR 56, inclusive of EO and ECH Residual Testing per ISO 10993-7.

Conclusion:

The subject devices are substantially equivalent to the predicate devices since it has the same intended use, indications for use, materials, design features, and sterilization to either all or one of the predicate devices. Non-clinical testing results support the substantial equivalence claim. Therefore, the subject devices are expected to perform adequately during clinical use.