July 30, 2021

Endeavor Orthopaedics, LLC
℅ Alyssa Thomas
Principal Consultant
Allegiance Regulatory Consulting LLC
16642 SW Lansford Ct.
Beaverton, Oregon 97007

Re: K203408
Trade/Device Name: Summit Patella Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, GAT
Dated: July 26, 2021
Received: July 28, 2021

Dear Alyssa Thomas:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K203408

Device Name

Summit Patella Plating System

Indications for Use *(Describe)*

The Summit Patella Plating System is indicated for use in surgical stabilization of patella fractures during open reduction internal fixation (ORIF) procedures in adults. Each system includes a plate, screws, surgical suture, and instruments that are provided in a sterile procedure kit and intended for single use.

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.

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This summary of 510(k) information is being submitted in accordance with the requirements of SMDA (Safe Medical Devices Act) 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K203408

Submitter Contact Information

Name: Endeavor Orthopaedics, LLC
Address: 11601 S. Richmond Avenue
Tulsa, OK USA
Phone: 217-721-0758

Contact: John Alleman

Date Prepared: July 30, 2021

Device Identification

Trade Name: Summit Patella Plating System

Common Names: Bone Fixation Plate & Non-absorbable Surgical Suture

Classification Name(s) & Reference(s): Primary Classification: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances & accessories

21 CFR 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture

Device Class: Class II

Product Code(s): HRS & GAT

Legally Marketed Predicate & Reference Devices

Primary Predicate Device: K992616 SDB Cerclage System (marketed by Synthes as "Orthopaedic Cable System")

Additional Predicates: K100006 HS Fiber (Polyblend) Suture
K201578 DePuy Synthes Variable Angle Locking Patella Plating System)

Device Description

The Endeavor Orthopaedics Summit Patella Plating System is a plating system used for fixation of patella fractures. The system includes implants and ancillary instruments needed for open reduction internal fixation (ORIF) of a patella fracture, packaged together in a single use sterile procedure kit. The kit provides a patella plate, locking screws, nonabsorbable sutures with needles and surgical instrumentation required for preparation of fracture fragments, manipulation/reduction of the patella, provisional fixation, plate placement and definitive fixation to the dorsal surface of the patella. The system is intended for single use, by a licensed orthopedic surgeon.

Intended Use / Indications for Use

The Summit Patella Plating System is indicated for use in surgical stabilization of patella fractures during open reduction internal fixation (ORIF) procedures in adults. Each system includes a plate, screws, surgical suture, and instruments that are provided in a sterile procedure kit and intended for single use.

Summary of Technological Characteristics

The Summit Patella Plating System includes plates, screws, sutures and instrumentation to provide the benefit of plating for patella fracture repair. The plates are available in two sizes. Each sterile procedure kit contains a plate, sutures with needles, locking screws and ancillary surgical instruments needed for stable repair of patella fractures. The patella plates are titanium alloy. The locking screws are manufactured from cobalt chrome and the suture is a polyblend suture with a stainless steel needle. The instruments within the procedure kit include K-wires, olive wires, drill bit, drill guides and a T8 driver and driver shaft. The characteristics associated with the plates, screws, sutures with needles and surgical instruments give the surgeon the standard features required for plating and suturing in one procedure kit. The kits are terminally sterilized by a validated electron beam radiation process.

Performance Data

Non-Clinical Testing – The application includes details associated with nonclinical testing. In all instances of the Summit Patella Plating System's components and construct testing the system performed as intended. The biocompatibility evaluation and testing performed demonstrate that the component materials, manufacturing processes and final packaging/sterilization processes are acceptable based on the contact category for the kit components. Construct/functional testing was done to compare the performance of the Summit plate's fixation to that of its predicate device. Summit system screw testing was completed, and aged suture strength was evaluated. The acceptance criteria were met during performance tests. Sterilization and packaging

testing validate the procedure kit's sterility and ability to protect the component within the Summit System. The nonclinical evaluations provide evidence of the Summit Patella Plating System's safety and effectiveness when used as intended.

Clinical Testing - Clinical testing is not included in this submission.

Substantial Equivalence

The Summit Patella Plating System provides a safe and effective device system to address both the bony components and soft-tissue components of a patella fractures, in a single surgical procedure kit. The Summit System and the predicate are both indicated for use in surgical repair of the patella. The Summit system has similar indications for use, materials, performance, labeling, packaging and sterilization as the predicate system. Both systems include titanium and cobalt chrome components. Both systems provide compression for patella fractures. The labeling content is similar for both device systems. Both systems include single-use radiation sterilized components. The FDA product codes for each system are different, i.e., HRS for plates and JDQ for cerclage; however, they both include metallic implantable devices for fracture compression. The Summit System uses a plate for fracture compress and the Synthes Cable System uses cerclage cabling around K-wires. The Summit patella plates have a smooth surface with rounded edges designed to help reduce soft tissue irritation. The crimp block included in the Cable system includes spikes for anchoring to the bone. The Summit System includes an optional cerclage type component, the sutures, for soft tissue fixation. The Cable System does not include optional components for soft tissue fixation. The differences between the two systems do not raise any new or different questions or issues related to safety or effectiveness, as evident by the discussions and testing provided within the application. The performance data demonstrates that the Summit Patella Plating System is as safe and effective as the Synthes Orthopaedic Cable System. Thus, the Summit Patella Plating System is substantially equivalent.

Conclusions

Conclusions drawn from the comparison to the predicate device and the nonclinical testing demonstrate that the Summit Patella Plating System is as safe, as effective, and performs as well as or better than the predicate device.