October 26, 2020

Advanced Orthopaedic Solutions, Inc.
% Jolie Krance
Senior Regulatory Affairs Specialist
Advanced Orthopaedic Solutions
3203 Kashiwa Street
Torrance, California 90505

Re: K202489
Trade/Device Name: AOS Fibonacci Lower Extremity Plating System – AOS Proximal Tibia 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
Dated: August 27, 2020
Received: August 31, 2020

Dear Jolie Krance:

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)*
K202489

Device Name
AOS Fibonacci Lower Extremity Plating System – Proximal Tibia Plates

Indications for Use *(Describe)*
The AOS Fibonacci Proximal Tibia Plating System is intended for the fixation of fractures, nonunions, malunions, osteopenic bone, and tibial osteotomies of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

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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ADVANCED ORTHOPAEDIC SOLUTIONS

510(k) Summary

Date Prepared	October 22, 2020
Submitted by	Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 Phone: (310) 533-9966
Establishment Registration	2032480
Owner Operator Number	9046896
Regulatory Contact	Jolie Krance Regulatory Affairs Manager Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 (310) 533-9966 jkrance@aosortho.com
Device Name	AOS Fibonacci Lower Extremity Plating System – AOS Proximal Tibia Plating System
Common Name	Plate, Fixation, Bone
Classification	Class 2 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Device Code	HRS — Plate, Fixation, Bone
Legally Marketed Substantially Equivalent Devices	Synthes LCP Proximal Tibia Plate Line Extension (K052390) (Primary) Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates (K082624)
Referenced Devices	AOS Small Fragment Plating System (K152732) AOS Galileo Trochanteric Nail System (K021008)

ADVANCED ORTHOPAEDIC SOLUTIONS

Device Description

The AOS Proximal Tibia Plating System consists of precontoured, single use, open reduction internal fixation Lateral Proximal Tibia Plates and Posteromedial Proximal Tibia Plates, manufactured from titanium alloy, and AOS Fibonacci screws 3.5mm in diameter or larger. These plates and screws, and their dedicated accessories and sterilization trays, will be added to the AOS Fibonacci Lower Extremity Plating System.

The 4.0mm Fixed Angle Locking Screws are single use titanium alloy orthopedic fixation screws, designed for use with all plates in the Fibonacci Lower Extremity Plating System, including the proximal tibia plates.

The 3.5mm Diamond Workhorse Screws are single use titanium alloy orthopedic fixation screws with a faceted cut core diameter, designed for use with all plates in the Fibonacci Lower Extremity Plating System, including the proximal tibia plates.

Indications for Use

The AOS Proximal Tibia Plating System is intended to be used for fixation of fractures, nonunions, malunions, osteopenic bone, and tibial osteotomies of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

Technological Characteristics

The AOS Proximal Tibia Plating System plates and screws are similar in geometry to the identified predicate. The Proximal Tibia Plates have a different material than the identified predicate device (the subject devices is manufactured from titanium alloy, compared to stainless steel or pure titanium), and are compatible with the subject screw with faceted cut core diameter (diamond cut screws). The performance requirements and method of operation of the subject device are identical to the predicate device.

Substantial Equivalence

The purpose of the Traditional 510(k) is to acquire clearance to market the AOS Proximal Tibia Plating System for inclusion into the AOS Fibonacci Lower Extremity Plating System by claiming substantial equivalence to the legally marketed predicate devices, the Synthes 4.5mm LCP Proximal Tibia Plates (K052390), and the Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates (K082426).

Nonclinical Testing

The AOS Proximal Tibia Plating System was subjected to internal engineering analysis, static and fatigue four-point bend testing per ASTM F382, and torsion strength, insertion torque, and pullout strength testing per ASTM F543. The results demonstrate that the AOS Proximal Tibia Plating System and accessories are substantially equivalent to the predicates.

Conclusion

Since the device has the same intended use and similar technological characteristics to the identified predicates, the device does not raise any different questions of safety or effectiveness. The performance testing and engineering analysis demonstrated that the subject device had substantially equivalent performance. Therefore, the premarket notification demonstrated that the device is substantially equivalent to the predicate.