July 18, 2019

Advanced Orthopaedic Solutions, Inc.
Elaine Nguyen
Regulatory Affairs Specialist
3203 Kashiwa Street
Torrance, California 90505

Re: K191598
Trade/Device Name: AOS ES™ Retrograde Femoral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 31, 2019
Received: June 17, 2019

Dear Ms. Nguyen:

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,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
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 below.

510(k) Number *(if known)*
K191598

Device Name
AOS ES™ Retrograde Femoral Nail

Indications for Use *(Describe)*
The AOS ES™ Retrograde Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, and tumor resections, supracondylar fractures, including those with severe comminution and intra- articular extension, ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, and fractures resulting from osteoporosis.

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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Special 510(k) Summary

Date Prepared	July 3, 2019
Submitted by	Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 Phone: (310) 533-9966
Establishment Registration	2032480
Owner Operator Number	9046896
Contact Person	Elaine Nguyen, Regulatory Affairs Specialist Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 (310) 533-9966 enguyen@aosortho.com
Device Name	AOS ES™ Retrograde Femoral Nail
Common Name	Internal Fixation
Classification	Class II, 21 CFR 888.3020 Intramedullary Fixation Rod
Device Code	HSB
Substantially Equivalent Devices	Primary: AOS Retrograde Femoral Nail (K132005, Cleared September 10, 2013) Secondary: AOS ES™ Trochanteric Nail (K103533, Cleared January 19, 2011)

Device Description	The AOS Extended Short™ (ES) Retrograde Femoral Nail is a single use, open reduction and internal fixation device, for the intramedullary fixation of fractures of the femur. The device is meant as a load sharing device, and it may be removed once the fracture has healed. The device consists of a nail, distal captured cortical and cancellous screws, proximal captured cortical screws, a locking spacer, fixation nuts and washers, and end caps.
Indication for Use	The AOS ES™ Retrograde Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures Pseudoarthrosis osteotomy Correction osteotomy Pathologic fractures and impending pathologic fractures Tumor resections Supracondylar fractures, including those with severe comminution and intra- articular extension Ipsilateral femur fractures Bone lengthening Fractures proximal to a total knee arthroplasty or prosthesis Fractures distal to a hip joint Non-unions and malunions Fractures resulting from osteoporosis.
Substantial Equivalence	The AOS ES™ Retrograde Nail and the AOS Retrograde Nail (K132005) have the same intended use, patient population, operating principle, and risk profile. They have identical manufacturing, packaging, sterilization parameters, and shipping processes, all of which will be conducted under the same quality management system.
Preclinical Testing	The AOS ES™ Retrograde Femoral Nail System was subjected to functional testing and strength comparison analysis. The results demonstrate that the AOS ES™ Retrograde Femoral Nails 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 equivalence performance. Therefore, the premarket notification demonstrated that the device is substantially equivalent to the predicate.