DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Inc. (AOS)
Alex Bhaskarla
Regulatory Affairs Manager
3203 Kashiwa St.
Torrance, California 90505

January 24, 2017

Re: K163014
Trade/Device Name: AOS Small Bone Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 7, 2016
Received: October 28, 2016

Dear Alex Bhaskarla:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163014

Device Name

AOS Small Bone Nailing System

Indications for Use *(Describe)*

The AOS Small Bone Nail System is intended for fixation of fractures and osteotomies of the fibula, radius and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

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

6. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: October 7, 2016

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:
Alex Bhaskarla
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS Small Bone Nail System

COMMON NAME: Intramedullary Fixation Rod/Pin

CLASSIFICATION: Class II, 21 CFR 888.3020, Intramedullary Fixation Rod/Pin

DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICES:

Synthes Elastic Intramedullary Nail (EIN)	K971783
Acumed Small Bone Locking Rod System II	K031438
Acumed Small Bone IM Nail System	K143276
Smith & Nephew Intramedullary Nail System	K983942

DEVICE DESCRIPTION: The AOS Small Bone Nail is a titanium alloy (Ti-6Al-4V) intramedullary nail available in various lengths (110mm to 260mm) and diameters (2.5mm to 5.0mm). The nail is compatible with use of 3.5mm and 2.7mm cortical locking screws that allow for additional fracture fixation and locking capabilities.

INDICATIONS FOR USE: The AOS Small Bone Nail System is intended for fixation of fractures and osteotomies of the fibula, radius and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the AOS Small Bone Nail System to the predicate devices. The proposed system has the same indications for use, is similar in shape and design, and has the same fundamental technology.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The AOS Small Bone Nailing System has the following similarities to the predicates:

- same device classification
- same lengths
- same material
- same anatomical sites
- same intended use
- same biocompatibility
- same shaft diameter
- same locking screw diameters

The AOS Small Bone Nailing System has longer cortical screws. Longer screw lengths provide more engagement with the bone. Mechanically, the subject nail proved stronger than the predicate device used for testing.

PRECLINICAL TESTING: The AOS Small Bone Nail System was subjected to comparative mechanical testing per a four point bend test based on ASTM F1264-14. The results demonstrate that the AOS Small Bone Nail are substantially equivalent to the predicates.

STANDARDS: Recognized industry standards are cited in the Standards Report

CLINICAL DATA: There is no clinical data referenced in this 510(k)

PERFORMANCE TESTING No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the AOS Small Bone Nail System was conducted in accordance with various international standards and internal AOS methods.