AOS
ADVANCED ORTHOPAEDIC SOLUTIONS

5. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: July 1, 2014

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

CONTACT PERSON:
Anna Hwang
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS 6.5mm Captured, Fully Threaded Cancellous Screw

COMMON NAME: Internal Fixation

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

DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICES: AOS Antegrade Femoral Nail System (510(k): K123569, Cleared May 24, 2013); DePuy ACE Universal and Troch Entry Femoral Nail Systems (510(k): K033329, Cleared November 14, 2003); and I.T.S. GMBH IM Nail Systems CFN-CTN-CHN (510(k): K132945, Cleared March 7, 2014)

DEVICE DESCRIPTION: The AOS 6.5mm Fully Threaded Cancellous Screw is used in the AOS Antegrade Femoral Nail System, in conjunction with the AOS Antegrade Femoral Nail. The screw can be used in both recon and antegrade configurations and can be threaded in and locked to the nail.

INDICATIONS FOR USE: The AOS Antegrade 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 intraarticular 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.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the AOS 6.5mm Fully Threaded Cancellous Screw 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.

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

July 8, 2014

Advanced Orthopaedic Solutions, Incorporated
Ms. Anna Hwang
3203 Kashiwa Street
Torrance, California 90505

Re: K141228
Trade/Device Name: AOS Antegrade Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 7, 2014
Received: May 12, 2014

Dear Ms. Hwang:

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" (21CFR 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 yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

4. INDICATIONS FOR USE STATEMENT

Traditional 510(k) Premarket Notification
Indication for Use Statement
AOS Antegrade Femoral Nail System

510(k) Number (if known): K141228

Device Name: AOS Antegrade Femoral Nail System

Indications for Use:

The AOS Antegrade 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 intraarticular extension
- Ipsilateral femur fractures
- Bone lengthening
- Fractures proximal to a total knee arthroplasty or prosthesis
- Fractures distal to a hip joint
- Nonunions and malunions
- Fractures resulting from osteoporosis

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

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