DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 14, 2016

Aesculap Implant Systems, LLC
Mr. Paul Amudala
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K162134
Trade/Device Name: ENNOVATE Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ
Dated: November 8, 2016
Received: November 14, 2016

Dear Mr. Amudala:

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)*

K162134

Device Name
ENNOVATE Spinal System

Indications for Use *(Describe)*

The ENNOVATE Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The ENNOVATE System can be used in both an Open and Minimally Invasive Surgery (MIS). The device is indicated for treatment of the following acute and chronic instabilities or deformities.

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies),
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation)
4. Spinal Stenosis,
5. Deformities or Curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

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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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Implant Systems* ENNOVATE *Spinal System
Nov 08, 2016

COMPANY: Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Paul Amudala

610-984-9303 (phone)
610-791-6882 (fax)

TRADE NAME: ENNOVATE Spinal System

COMMON NAME: ENNOVATE Spinal System

REGULATION NUMBER: 888.3070 – Pedicle screw spinal system

PRODUCT CODE: NKB, MNI, MNH, and KWQ

CLASS: Class III

REVIEW PANEL: Orthopedics

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the ENNOVATE Spinal System is substantially equivalent to the Primary Predicate K130291 S4 Spinal System (including K123939, K123352, K112551, K100623, K090657, K071945, K062085, and K032219), and the Additional Predicates EXPEDIUM® Spinal System (K090230,K082942, K041119, K073364, and K070300), and Polaris™ Spinal System (K151974, K133746, K123549, K090203, and K111957).

DEVICE DESCRIPTION

The ENNOVATE Spinal System is an implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. This system includes polyaxial screws of varying diameters and lengths, rod-to-rod and cross connectors of various styles and lengths. All implant components are top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V), conforming to ISO 5832-3.

The ENNOVATE Spinal System is a spinal rod and screw system. This system's polyaxial screws can be rigidly locked into a wide range of configurations, therefore allowing each construct to be formed to the needs of an individual patient. Rods of this system may be shaped intraoperatively to correct or maintain proper spinal curvature.

INDICATIONS FOR USE

The ENNOVATE Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended

to be used as an adjunct to fusion using autograft or allograft. The ENNOVATE System can be used in both an Open and Minimally Invasive Surgery (MIS). The device is indicated for treatment of the following acute and chronic instabilities or deformities.

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3. Trauma (i.e., fracture or dislocation)
4. Spinal Stenosis,
5. Deformities or Curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The components of the ENNOVATE Spinal System are offered in similar configuration as the predicate devices. All of the implants are made from a Titanium Alloy (Ti-6Al-4V). The instruments are made of medical grade silicone, stainless steel, titanium alloy and PEEK which are the same materials as the Primary and Reference Predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the guidance "Spinal System 510(k)s May 3, 2004" was completed where applicable.

- Dynamic/Static compression tests and static torsion tests per ASTM F1717-15.
- Dynamic compression/tension test per ASTM F2193-14.
- Dynamic/Static flexion bending tests, Static rod grip and Static rod/cross rod torsion tests per ASTM F1798-13.
- Axial compression, pull out strength, driving torque test per ASTM F543-13.

CONCLUSION:

Aesculap believes that based on the completed testing, the Ennovate Spinal System presented in this submission is substantially equivalent in design, materials, intended use, and performs as safely and effectively as the primary predicate and reference predicates currently on the market.