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

July 19, 2021

Re: K210963
Trade/Device Name: ENNOVATE® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: May 20, 2021
Received: May 21, 2021

Dear Paul 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. 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

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K210963

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

Aesculap Implant Systems* ENNOVATE *Spinal System
Mar 30, 2021

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

CONTACT: Paul Amudala
Sr. Regulatory Affairs Specialist
610-984-9303 (phone)
610-791-6882 (fax)

TRADE NAME:	ENNOVATE® Spinal System
COMMON NAME:	Thoracolumbosacral pedicle screw system
REGULATION NUMBER:	Thoracolumbosacral pedicle screw system (21 CFR 888.3070) Spinal interlaminal fixation orthosis (21 CFR 888.3050) Spinal intervertebral body fixation orthosis (21 CFR 888.3060)
PRODUCT CLASS:	Class II
PRODUCT CODE:	NKB, KWQ, KWP
REVIEW PANEL:	Orthopedics

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the ENNOVATE Spinal System is substantially equivalent to the Primary Predicate S4 Spinal System (K130291) and Additional Predicates ENNOVATE Spinal System (K180433), Everest Spinal System (K151727), EXPEDIUM® Spinal System (K130877), and Polaris™ Spinal System (K151974).

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 screws of varying types, diameters and lengths, hooks, rods, rod-to-rod connectors, lateral offset 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 as well as CoCr alloy conforming to ISO 5832-12.

The ENNOVATE Spinal System is a spinal rod and screw system. This system's 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. All screws within this system are not intended for use with bone cement. Rods of this system may be shaped intraoperatively to correct or maintain proper spinal curvature. The hooks have curved blades underneath the head portion of the implant that wrap around posterior anatomy of the spine to provide an alternative method of anchoring the rod to the spine.

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.

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

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

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

PERFORMANCE DATA

To support substantial equivalence, biomechanical testing was completed per the "Spinal System 510(k)s May 3, 2004" for the products within this submission where applicable.

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

The presence of endotoxins is tested with the LAL gel clot method with the acceptance criteria of <20 EU/device per United States Pharmacopea (USP).

CONCLUSION:

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