July 1, 2022

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

Re: K213871
Trade/Device Name: Ennovate Cervical Spinal and Occiput System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 1, 2022
Received: June 3, 2022

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)*
K213871

Device Name
Ennovate Cervical Spinal and Occiput System

Indications for Use *(Describe)*
The Aesculap Ennovate Cervical Spinal and Occiput System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (Cl to C7) and the thoracic spine (Tl-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Aesculap Ennovate Cervical Spinal and Occiput System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Aesculap Ennovate Lumbar System may be connected to the Aesculap Ennovate Cervical Spinal and Occiput System using connectors and rods.

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 ENNOVATE Cervical Spinal and Occiput System
Jun 01, 2022

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

CONTACT: Paul Amudala
Sr. Regulatory Affairs Specialist
610-984-9303/610-417-0839 (phone)
610-791-6882 (fax)

TRADE NAME: ENNOVATE® Cervical Spinal and Occiput System

COMMON NAME: Posterior Cervical Screw System, Spinal Interlaminal Fixation Orthosis

REGULATION NUMBER: 21 CFR 888.3075 – Posterior cervical screw system
21 CFR 888.3050 – Spinal interlaminal fixation orthosis

PRODUCT CLASS: Class II

PRODUCT CODE: NKG, KWP

REVIEW PANEL: Orthopedics

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the ENNOVATE Cervical Spinal and Occiput System is substantially equivalent to the Primary Predicate K151938 S4C Cervical Spinal and Occiput Systems.

DEVICE DESCRIPTION

The Aesculap ENNOVATE Cervical Spinal and Occiput System is implant systems used to facilitate the biological process of spinal fusion. This system is intended to promote fusion of the cervical and thoracic spine (C1-T3) and occipito-cervico-thoracic junction (occiput-T3). The Aesculap ENNOVATE Cervical Spinal and Occiput System consist of various plates, screws, rods, hooks, and connectors.

INDICATIONS FOR USE

The Aesculap ENNOVATE Cervical Spinal and Occiput System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following

acute and chronic instabilities of the craniocervical junction, the cervical spine (Cl to C7) and the thoracic spine (Tl-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Aesculap ENNOVATE Cervical Spinal and Occiput System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Aesculap Ennovate Lumbar System may be connected to the Aesculap ENNOVATE Cervical Spinal and Occiput System using connectors and rods.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The components of the ENNOVATE Cervical Spinal and Occiput System are offered in similar configuration as the predicate device. All of the implants are made from a Titanium Alloy (Ti-6Al-4V) and CoCr. The instruments are made of medical grade stainless steel, aluminum, titanium alloy, PEEK and silicone which are the same materials as the Primary Predicate device and other Aesculap spine products distributed currently on the market.

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.

- ASTM F1717-18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.
- ASTM F1798-13 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.
- ASTM F2193-18a Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System.
- ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws.

CONCLUSION:

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