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

July 8, 2016

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

Re: K153700
Trade/Device Name: Aesculap® Implant Systems (AIS) S4 Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: June 3, 2016
Received: June 6, 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 Parts 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,

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)*

K153700

Device Name

AIS S4 Navigation Instruments

Indications for Use *(Describe)*

The AIS S4 Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure , such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion during the navigation of polyaxial screws (T1-T3).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

Aesculap® Implant Systems (AIS) S4 Spinal System

Jul 07, 2016

COMPANY: Aesculap® Implant Systems (AIS), LLC.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Paul Amudala, Regulatory Affairs Specialist
610-984-9303 (phone)
610-791-6882 (fax)
paul.amudala@aesculap.com

TRADE NAME: AIS S4 Navigation Instruments
COMMON NAME: Stereotaxic Instrument

REGULATION NUMBER: 882.4560 – Instrument, Stereotaxic

PRODUCT CODE: OLO and HAW
REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

The AIS S4 Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion during the navigation of polyaxial screws (T1-T3).

DEVICE DESCRIPTION

The AIS S4 Navigation Instruments are manual surgical instruments which are designed to interface with BrainLAB's already cleared surgical navigation systems. Instruments in this system may be pre-calibrated or manually calibrated to already cleared systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general or manual functions within the orthopedic surgical environment.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The AIS S4 Navigation Instruments have similar design features, materials, and indications for use as the current AIS manual instruments and are substantially equivalent to the instruments used with the BrainLAB's various navigation systems. The polyaxial screws can be placed in the thoracic spine (T1-T3) only. Screws are not intended to be placed in the cervical spine.

K153700

PERFORMANCE DATA

BrainLAB conducted validation activities including usability testing with the AIS S4 Navigation Instruments. The AIS S4 Navigation Instruments met the performance requirements. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the additional AIS S4 Navigation Instruments.

PREDICATE DEVICES

- K130887 – AIS S4 Cervical Navigation Instruments (Primary)

Reference Predicates:

- K070106 – BrainLAB VectorVision Fluro3D / Spine & Trauma 3D
- K053159 – VectorVision Spine
- K042721 – Kolibri Spine
- K062358 –Trauma
- K083310 –Spine & Trauma iCT
- K110204 –Spine & Trauma 2D / Fluro Express

CONCULSION

Aesculap believes that the instruments presented in this submission are substantially equivalent in design, materials, intended use, and perform as safe and effective as Aesculap's currently marketed devices.