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

Aesculap® Implant Systems (AIS) S4 Spinal System
August 6, 2013

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

CONTACT: Lisa M. Boyle, Sr Regulatory Affairs Specialist
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AUG 13 2013

TRADE NAME: AIS S4 Cervical 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 Cervical 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 pedicle screws (T1-T3).

DEVICE DESCRIPTION

The AIS S4 Cervical 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 Cervical Navigation Instruments have similar design features, materials, and indications for use as the current AIS manual instruments (class I instrumentation)

and are substantially equivalent to the instruments used with the BrainLAB's various navigation systems. The use of the navigated polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

PERFORMANCE DATA

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

PREDICATE DEVICES

- VectorVision Spine – K053159
- Kolibri Spine – K042721
- Trauma – K062358
- VectorVision Fluoro3D – K070106
- Spine & Trauma iCT – K083310
- BrainLab Trauma - 1100204
- Spine & Trauma 3D – K070106
- Spine & Trauma 2D / Fluro Express – K110204
- Aesculap S4C Spinal System (K050797, K060152, K062327)

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

August 13, 2013

Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K130887
Trade/Device Name: Aesculap S4 Cervical Navigation Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: June 13, 2013
Received: June 14, 2013

Dear Ms. Boyle:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

For

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K130887

Device Name: Aesculap S4 Cervical Navigation Instrumentation

Indications for Use:

The Aesculap S4 Cervical 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 pedicle screws (T1-T3).

Prescription Use __X__ and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130887