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

May 16, 2016

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

Re: K153396
Trade/Device Name: OrthoPilot® Next Generation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 12, 2016
Received: April 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 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,

Lori A. Wiggins -S

for

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)*

K153396

Device Name
OrthoPilot® Next Generation

Indications for Use *(Describe)*

The OrthoPilot® Next Generation Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to position endoprosthesis in arthroplasty in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for endoprosthesis replacement surgery (such as total knee, revision knee, unicondylar knee, and total hip systems) and provides intraoperative measurements of bone alignment. It indicates angles and positions for implant placement.

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

Aesculap OrthoPilot® Next Generation

Apr 12, 2016

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

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

DEVICE

TRADE NAME: Aesculap OrthoPilot® Next Generation

COMMON NAME: Surgical Navigation Platform

DEVICE CLASS: Class II

PRODUCT CODE: OLO

REGULATION NUMBER: 882.4560

CLASSIFICATION NAME: Orthopedic Stereotaxic Instrument

REVIEW PANEL: Orthopedic

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, L.L.C. believes that the updates to OrthoPilot® Next Generation TKA, TKR, and UKA software modules are substantially equivalent to the currently marketed OrthoPilot® Next Generation UKA software module cleared in the primary predicate K090375; OrthoPilot® Next Generation TKA & TKR software modules cleared in reference predicate K080547 and the CAP markers/Polaris Spectra 14 camera cleared in reference predicate K141694.

DEVICE DESCRIPTION

Aesculap's OrthoPilot® Next Generation is a computer assisted surgical navigation system that uses proprietary software to provide anatomical information to a surgeon. The hardware in the system consists of the following primary components: stereotaxic camera, computer (w/ monitors), rigid bodies (transmitters), passive markers, power supply, various tagged instruments, transport cart and stand. The computer accepts input from the transmitters on the rigid bodies either mounted to the patients bones or mobile to palpate anatomical landmarks in conjunction with a camera to monitor the spatial location of the transmitters in relation to each

other and/or instruments. The software modules for the OrthoPilot® Next Generation consist of modules for both a knee suite and a hip suite.

INDICATIONS FOR USE

The OrthoPilot® Next Generation Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to position endoprosthesis in arthroplasty in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for endoprosthesis replacement surgery (such as total knee, revision knee, unicondylar knee, and total hip systems) and provides intraoperative measurements of bone alignment. It indicates angles and positions for implant placement.

TECHNOLOGICAL CHARACTERISTICS (Compared to the Predicate)

OrthoPilot® Next Generation navigation system was originally cleared under K080547 and recent subsequently updates cleared under K141694.The intended use and fundamental scientific technology of the OrthoPilot® Next Generation Navigation system remain unchanged including the integration of passive marker spheres cleared as part of K141694. The only difference is an update to the knee software modules (TKA, TKR and UKA) for the integration of passive marker spheres cleared as part of K141694 and the other minor improvements.

PERFORMANCE DATA

OrthoPilot® Next Generation navigation system was developed in accordance with 'General Principles of Software Final Guidance for Industry and FDA Staff'; 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices' and Aesculap's procedures. There is no change to previous performance data for the OrthoPilot® Next Generation navigation system.

In addition, the software updates continue to comply with:

IEC 62304	International Electrotechnical Commission Medical Device Software – Software Life Cycle Processes