



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

AESCULAP IMPLANT SYSTEMS, LLC
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

February 24, 2015

Re: K141694
Trade/Device Name: Aesculap OrthoPilot Next Generation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 27, 2015
Received: January 28, 2015

Dear Ms. Wing:

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 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

Indications for Use

510(k) Number (if known)
K141694

Device Name
Aesculap 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

B. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Aesculap OrthoPilot Next Generation

January 27, 2015

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

CONTACT: Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
Julie.TomWing@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 the introduction of alternate marker spheres, a camera update and software integration of OrthoPilot® Next Generation navigation system remains substantially equivalent to the currently marketed OrthoPilot Next Generation system previously cleared in 510(K) K090375.

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, an ultrasound module, 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 computer can also accept spatial input for anatomical landmarks from an ultrasound unit. 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 cleared under K090375.

The intended use and fundamental scientific technology of the OrthoPilot® Next Generation Navigation system remain unchanged. The only difference is a design modification of the passive marker spheres and it's integration with the current software modules.

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.

As a result of the risk assessment, design modification of the marker spheres and it's integration with the current software modules was verified and validated via sterilization; shelf life; navigation performance; software acceptance tests and software life cycle testing.

In addition, Aesculap's OrthoPilot® Next Generation navigation platform complies with the following internationally recognized standards:

IEC 60601-1	International Electrotechnical Commission Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 62304	International Electrotechnical Commission Medical Device Software – Software Life Cycle Processes
ISO 14971	International Standards Organization Medical Devices – Application of Risk Management to Medical Devices