K090375

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(in Accordance with SMDA of 1990)

JUN 23 2009

Aesculap Orthopilot Next Generation
April 3, 2009

COMPANY:	Aesculap®Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Lisa M. Boyle 800-258-1946 x 5274 (phone) 610-791-6882 (fax)
TRADE NAME:	Aesculap Orthopilot Next Generation
COMMON NAME:	Surgical Navigation Platform
DEVICE CLASS:	Class II
PRODUCT CODE:	OLO
CLASSIFICATION:	882.4560 – Orthopedic Stereotaxic Instrument
REVIEW PANEL:	Orthopedic

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.

DEVICE DESCRIPTION

Aesculap's OrthoPilot Next Generation is a computer assisted surgical navigation system that uses proprietary software to provide optimal anatomical information to a surgeon. The hardware in the system consists of the following primary components: stereotaxic camera, computer (w/ monitors), rigid bodies (transmitters), 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 also can 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.

PERFORMANCE DATA

No applicable performance standards have been promulgated under FDCA Section 514 for this system. The previously cleared software modules were developed in accordance with Aesculap's internal SOP's as well as CDRH's "General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the OrthoPilot Unicondylar Knee Arthroscopy (UKA) software module is substantially equivalent to our currently marketed OrthoPilot Total Knee Arthroscopy (TKA) software module cleared in Aesculap's 510(k) submission #K080547.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Aesculap Implant System, Incorporated
% Ms. Lisa M. Boyle
Sr. Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K090375
Trade/Device Name: Aesculap Orthopilot Next Generation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotactic Instrument
Regulatory Class: II
Product Code: OLO
Dated: May 18, 2009
Received: May 20, 2009

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.

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.

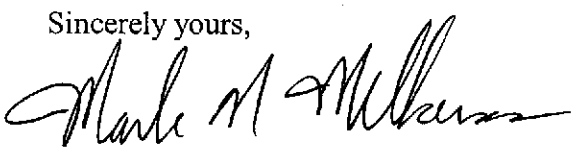
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K090375

Device Name: Aesculap Orthopilot Next Generation

Indication 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090375