APR 0 4 2002

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	AESCULAP®, INC. OCTOBER 23, 2001

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Trade Name: Orthopilot® 2

Common Name(s): Orthopilot® 2 Navigation Platform

Classification Name(s): Stereotaxic Instrument

Establishment Name & Registration Number:

Name: Aesculap®, Inc.
Number: 2916714

Classification: 21 CFR Section 882.5550

Device Class: Class II
Classification Panel: Neurology
Product Code(s): HAW

Applicant Name & Address:
Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Company Contact:
Georg Keller
Regulatory Affairs Manager
800/258-1946 x 5073 (phone)
610/791-6882 (fax)

Indications for Use
The Orthopilot® 2 Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to optimally position endoprosthesis in arthroplasty such as the Search Evolution Knee system and the Gem Knee system in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for total endoprosthesis replacement surgery and provides intraoperative measurements of bone alignment. It indicates optimized angles and positions for implant placement. *(Does not include an indication for High Tibial Osteotomy (HTO) module).*

Device Description
Orthopilot® 2 Navigation Platform uses transmitters that are mounted to the patients bones, or are flexible to palpate landmarks and a camera to monitor the spatial location of those transmitters in relation to each other and the medical instruments. These locations are used to locate the centers of rotation of the femur head, ankle, knee. These measurements allow for greater accuracy than mechanical methods of ascertaining implantation sites and positions.

Performance Standards (Section 514 compliance):
No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. However, Aesculap's Orthopilot® 2 Navigation Platform complies with the following standards, which appear, on the FDA List of Recognized Consensus Standards:

IEC 60601-1	International Electrotechnical Commission; Medical Electrical Equipment, Part 1: General Requirements for Safety.
IEC 60601-1-2	International Electrotechnical Commission; Medical Electrical Equipment, General Requirements for Safety: Electromagnetic Compatibility - Requirements and Tests.

In addition, the Orthopilot® 2 Navigation Platform meets the requirements of the following Canadian Standard Association standard.

CAN/CSA- C22.2 No. 601.1-M90	Medical Electrical Equipment, Part 1: General Requirements for Safety

Labeling:
The Aesculap's Orthopilot® 2 Navigation Platform discussed in this premarket notification will be manufactured and labeled with the Aesculap® logo. The system will be marketed exclusively to healthcare facilities and physicians.

Substantial Equivalence:
Aesculap's Orthopilot® 2 Navigation Platform is substantially equivalent to existing devices cleared by FDA. They are as follows:

- Orthopilot® (K003347)
- Stryker Navigation System-Knee Module (K010204)
- Brainlab Vector Vision Knee (K010612)
- Brainlab Vector Vision Hip (K010602)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap, Inc.
Mr. Georg Keller
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

APR 0 4 2002

Re: K013569
Trade Name: Orthopilot 2
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 22, 2002
Received: January 23, 2002

Dear Mr. Keller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K013569

Device Name: **Orthopilot® 2 Navigation Platform**

Indication for Use:

The Orthopilot® 2 Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to optimally position endoprosthesis in arthroplasty such as the Search Evolution Knee system and the Gem Knee system in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for total endoprosthesis replacement surgery and provides intraoperative measurements of bone alignment. It indicates optimized angles and positions for implant placement. (*Does not include an indication for High Tibial Osteotomy (HTO) module).*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013569

Prescription Use X or Over-the-Counter Use _____