K102505

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

High Tibial Osteotomy (HTO) Plating System
November 15, 2010

NOV 2 4 2010

COMPANY:	Aesculap Implant Systems, LLC 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Kathy A. Racosky (610) 984-9291 (phone) 610-791-6882 (fax)
TRADE NAME:	HTO Plating System
COMMON NAME:	High Tibial Osteotomy (HTO) Plating System
CLASSIFICATION NAME:	Plate, Fixation, Bone (HRS) Screw, Fixation, bone (HWC)
REGULATION NUMBER:	888.3030, 888.3040

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the new HTO Maxi plate and screws are substantially equivalent to the existing plate and screws of the High Tibial Osteotomy (HTO) Plating System cleared under K080992.

DEVICE DESCRIPTION

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System which consists of tapered plates, screws (cancellous and cortical design), and spacer blocks in various sizes. The plate in this system accepts 6 mm cancellous screws proximally and 4.5 mm cortical screw distally. The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is manufactured from Titanium/Titanium Alloy and will be provided sterile.

INDICATIONS FOR USE

There have been **no changes to the Indications for Use**. It remains as follows:

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

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PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the new HTO Maxi Plate and screws which are being added to the Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems HTO Plating System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared high tibial osteotomy systems with similar indications.

PERFORMANCE DATA

Fatigue testing of the Position HTO Maxi Plate was performed to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Aesculap Implant Systems, LLC
% Ms. Kathy Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 2 4 2010

Re: K102505
Trade/Device Name: Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 15, 2010
Received: November 17, 2010

Dear Ms. Racosky:

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

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/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,

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

NOV 2 4 2010

510(k) Number: K102505

Device Name: Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System

Indications for Use:

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

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)

for MXM

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

510(k) Number K102505

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