K101937

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

Hybrid Trocar System
July 6, 2010

AUG 11 2010

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Denise R. Adams
800-258-1946 ext. 5076 (phone)
610-791-6882 (fax)
Denise.Adams@aesculap.com

COMMON NAME: Trocar

CLASSIFICATION NAME: Trocar

REGULATION NUMBER: *876.5090*

PRODUCT CODE: FBQ

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the modified trocars and accessories are substantially equivalent to the existing components of the Aesculap Trocar Instrument Set (Interchangeable) (K942053) and Aesculap Needlescopic Instrument System (K982623) and VECTEC's Disposable Trocars (K071976).

DEVICE DESCRIPTION

Aesculap's Hybrid Trocar System can be used in laparoscopic general surgery, gynecology, and urology. The trocars are made from biocompatible materials. They are available as reusable or disposable in 3.5, 5, 10 or 12mm diameter with lengths of 60, 110, and 150mm. The trocars are offered with or without a stopcock, and threaded or smooth. The devices are color coded for easy identification.

INDICATIONS FOR USE

The endoscopic instruments presented in this submission are for use in laparoscopy (abdominal and gynecological surgery) for puncture of the abdominal cavity and establishment of a port of entry for endoscopic instruments.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

The new trocars in the Hybrid Trocar System are offered in similar shapes and sizes as the predicate devices. All the components are manufactured from Stainless Steel and PEEK for the reusable and Polycarbonate for the disposable.

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PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug, and Cosmetic Act for these devices.

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

AUG 11 2010

Aesculap®, Inc.
% Ms. Denise Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K101937
Trade/Device Name: Aesculap Hybrid Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 06, 2010
Received: July 12, 2010

Dear Ms. Adams:

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 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,

for

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

Enclosure

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A. INDICATIONS FOR USE STATEMENT

AUG 11 2010

510(k) Number:_____

Device Name: Aesculap Hybrid Trocars

Indications for Use:

The endoscopic instruments presented in this submission are for use in laparoscopy (abdominal and gynecological surgery) for puncture of the abdominal cavity and establishment of a port of entry for endoscopic instruments.

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)

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

510(k) Number K101937