K123102

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

Sovereign® mini System
September 28, 2012

JAN 0 3 2013

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

CONTACT: Denise R. Adams
610-984-9076
610-791-6882 (fax)
denise.adams@aesculap.com

COMMON NAME: Laparoscope, General and Plastic Surgery

CLASSIFICATION NAME: Endoscope and Accessories

REGULATION NUMBER: 21 CFR 876.1500

PRODUCT CODE: GCJ

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the modified components of the Sovereign® mini system are substantially equivalent to the components of the Aesculap Needlescopic Instrument System (K982623).

DEVICE DESCRIPTION

Aesculap's Sovereign® mini system can be used in adult and pediatric laparoscopic general surgery. The system consists of modular forceps and scissors in lengths of 200 and 290 millimeters with interchangeable ratcheting and non-ratcheting handles. The system also includes reusable trocars and trocar pins. The trocars and trocar pins are available in 3.5 millimeter diameter and 60 and 110 millimeter lengths, and 5 millimeter diameter and 60,110 and 150 millimeter lengths with or without a stopcock. The 3.5mm trocars are for use with the 3.5mm instruments, and the 5mm trocars accommodate 4 and 5mm endoscopes. The instruments and trocars are composed of stainless steel and PEEK materials.

INDICATIONS FOR USE

Aesculap's Sovereign® mini system is indicated for use in adult and pediatric diagnostic and therapeutic general endoscopy and laparoscopy surgery.

TECHNOLOGICAL CHARACTERISTICS

The modified instruments have the same technological characteristics as the predicate devices. They are similar in design and size, manufactured from the same materials, and have monopolar capabilities.

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 Center – WO66-G609
Silver Spring, MD 20993-0002

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

January 3, 2012

Re: K123102
Trade/Device Name: Aesculap Sovereign® mini System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 01, 2012
Received: December 04, 2012

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,

Peter D. Rumm -S

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K123102

Device Name: Aesculap Sovereign® mini System

Indications for Use:

Aesculap's Sovereign® mini system is indicated for use in adult and pediatric diagnostic and therapeutic general endoscopy and laparoscopy surgery.

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)

Dwight Yen
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(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123102