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

May 26, 2016

Aesculap, Inc.
Ms. Jessica Stigliano
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K160393
Trade/Device Name: AdTec
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 18, 2016
Received: March 21, 2016

Dear Ms. Jessica Stigliano:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160393

Device Name
AdTec®

Indications for Use *(Describe)*
Aesculap's AdTec® is indicated for use in adult and pediatric (3.5mm instruments only) diagnostic and therapeutic general endoscopy and laparoscopy surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

AdTec®
February 8, 2016

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

CONTACT: Jessica Stigliano
610-984-9063
610-791-6882 (fax)
jessica.stigliano@aesculap.com

COMMON NAME: Laparoscope, General and Plastic Surgery

CLASSIFICATION NAME: Endoscope and Accessories

REGULATION NUMBER: 876.1500

PRODUCT CODE: GCJ

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes the modified components of AdTec® are substantially equivalent to the components of the Aesculap Sovereign® mini System (K123102), Aesculap Endoscopic Instruments (K940936) and Aesculap Sovereign® Bipolar Instruments (K001330).

DEVICE DESCRIPTION

AdTec® is indicated for use in adult and pediatric diagnostic and therapeutic general endoscopy and laparoscopy surgery. The system consists of single-use and reusable forceps, clamps, and scissors made of Stainless Steel with monopolar or bipolar capabilities. They facilitate in the grasping, cutting, and manipulation of soft tissue and blood vessels during laparoscopic procedures. The single-use instruments come completely assembled in one single piece, and are available in various lengths ranging from 220mm – 420mm. The reusable instruments are modular and consist of a jaw insert and an insulated outer tube with interchangeable ratcheting and non-ratcheting handles. They are also available in lengths ranging from 220mm – 420mm. The system also includes a single use trocar sleeve and a reusable trocar pin. The trocar sleeve is made of Grilon, and the trocar pin is made of Stainless Steel and PEEK. The trocar sleeve and trocar pin are available in a 3.5mm diameter and a 70mm length. They are accessories for the 3.5mm trocars cleared under K123102.

INDICATIONS FOR USE

Aesculap's AdTec® system is indicated for use in adult and pediatric (3.5mm instruments only) diagnostic and therapeutic general endoscopy and laparoscopy surgery.

TECHNOLOGICAL CHARACTERISTICS

As is established in this submission, Aesculap's AdTec is substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, intended use, material composition, function and range of sizes.

PERFORMANCE DATA

The modifications to the subject submission were evaluated using a failure mode and effects (FMEA) risk analysis and no new risks were identified.

The use of these devices in adults and pediatric (3.5mm instruments only) diagnostic and therapeutic general endoscopy and laparoscopy surgery does not effect the risk analysis included in the submission of the primary predicate (K123102).

PRIMARY PREDICATE

- Aesculap Sovereign® mini System (K123102)

REFERENCE DEVICES

- Endoscopic Scissors, Forceps, Needleholders (K940936)
- Sovereign Bipolar mini System (K001330)

CONCULSION

Aesculap believes that the instruments presented in this submission are substantially equivalent in design, material, and indications for use to Aesculap's currently marketed devices presented in the revised 510(k) summary.