February 20, 2018

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

Re: K170683
Trade/Device Name: Aesculap Video Assisted Thoracic Surgery (VATS) Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 12, 2018
Received: January 16, 2018

Dear 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170683

Device Name
Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments

Indications for Use *(Describe)*
Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments are intended for use in open or thoracoscopic surgical procedures. They are designed for cutting, manipulating, grasping, clamping, dissecting or suction.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K170683

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

Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments

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

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

TRADE NAME: Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments

COMMON NAME: Laparoscope, General & Plastic Surgery/Minimally Invasive Surgical Instruments

REGULATION NUMBER: 876.1500 – Endoscope and accessories

PRODUCT CODE: GCJ

REVIEW PANEL: Gastroenterology and Urology

PRIMARY PREDICATE

- Aesculap® Thoracoscopic Instruments - K944955

REFERENCE DEVICE

- AdTec® – K160393
- Integra™Jarit® Video Assisted Thoracic Instruments – K120012

DEVICE DESCRIPTION

Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments are designed for cutting, manipulating, grasping, clamping, dissecting, or suction during open, mini-open, or thoracoscopic surgical procedures. The instruments are reusable and are made from Stainless Steel with monopolar capabilities. The instruments are modular, consisting of a jaw insert and insulated outer tube with interchangeable ratcheting and non-ratcheting handles. The instruments are 250mm in length with a 7mm diameter.

The instruments can be used interchangeably with either a ratcheting or non-ratcheting handle. The handles are made from PEEK with a HF connection that fits any standard monopolar cable.

The instruments can be used with a visualization system to allow for better visibility during the procedure. This is an independent system and is not system specific. No new visualization systems are being introduced by Aesculap® in this submission.

INDICATIONS FOR USE

Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments are intended for use in open or thoracoscopic surgical procedures. They are designed for cutting, manipulating, grasping, clamping, dissecting or suction.

TECHNOLOGICAL CHARACTERISTICS (compared to Primary Predicate and reference devices)

Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments are substantially equivalent to the primary predicate Aesculap® Thoracoscopic Instruments (K944955) and comparable to the reference devices, AdTec® (K160393) and Integra™Jarit® Video Assisted Thoracic Surgery (VATS) Instruments (K120012). The table below provides a comparison between the subject device and primary predicate and reference devices. The minor differences in technological characteristics do not raise questions of safety or effectiveness, as confirmed by the testing and validation activities described in the submission.

	New device Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments	**Primary Predicate device** Aesculap® Thoracoscopic Instruments (K944955)	**Reference device** AdTec®(K160393)	**Reference device** Integra™Jarit® Video Assisted Thoracic Surgery (VATS) Instruments (K120012)
Indications	Aesculap® VATS Instruments are intended for use in open, mini-open, or thoracoscopic surgical procedures. They are designed for cutting, manipulation, grasping, clamping, dissecting, or suction.	Aesculap® Thoracoscopic Instruments are intended for use in thoracoscopy. They are used to cut, manipulate, grasp, suture, ligate, suction, irrigate, and/or cauterize selected tissue.	Aesculap®'s AdTec® system is indicated for use in adult and pediatric (3.5mm instruments only) diagnostic and therapeutic general endoscopy and laparoscopy surgery.	Integra™Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are manually operated instruments designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, draining, aspirating, suturing, or ligating during open, mini-open, or thoracoscopic procedures.
Instruments:				
Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Features	• Modular • Insulated • Reusable • Monopolar capability	• Modular & non-modular • Reusable • Insulated • Selected monopolar capability	• Modular • Insulated • Reusable/disposable • Monopolar/bipolar capabilities	• Single or dual pivot • Reusable • Manually operated
Types	• Scissors • Forceps • Needleholders • Clamps • Dissectors • Suction/Irrigation	• Scissors • Forceps • Needleholders • Clamps • Dissectors • Suction/Irrigation	• Scissors • Forceps • Clamps • Suction/Irrigation	• Scissors • Forceps • Clamps • Dissectors • Needleholders • Suction/Irrigation
Dimensions	Length: 250mm Diameter: 7mm	Length: 220mm – 450mm Diameter: 5mm – 10mm	Length: 220 – 420mm Diameter: 3.5, 5, and 10mm	Length: 227mm – 500mm Diameter: 5mm – 10mm
Handles:				
Style	• Ring Handle • Ratcheted and non-ratcheted	• Ring handle • Ratcheted and non-ratcheted	• Ring handle axial or angled • Ratcheted/non-ratcheted	• Curved and straight • Ratcheted and non-ratcheted
Material	PEEK	Stainless Steel	PEEK	Stainless Steel
Insulation tube:				
Material	PEEK	Teflon	PEEK	N/A

PERFORMANCE DATA

Design Verification

The following design verification testing was completed for the Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments:

Test	Test Purpose	Results
Blocking function	Demonstrates single actuating element allows for temporary actuation of the barrier and latching and unlocking of the barrier	Pass
Cutting capacity	Demonstrates a smooth cut and that there is no plucking during the cutting performance	Pass
Holding force	Demonstrates a comparable holding force as the reference model	Pass
Preparation	Demonstrates the sufficient stability and ability to hold the maximum load to ensure adequate performance and work properly and safely in clinical use	Pass

The results of the design verification testing demonstrate that the Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments meet the pre-defined acceptance criteria and intended uses.

Electrical Safety

The Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments conform to the following electrical safety and EMC standards;

- IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

- IEC 60601-2-2_International Electrotechnical Commission, Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Conductivity testing

Conductivity testing according to IEC 60601-2-2 was performed to determine the electrical conductivity of the Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments. Results of the testing show that the instrument design is able to support application of HF current.

Biocompatibility

The contact classification for the Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments is surface contact less than 24 hours. Surgical grade stainless steel (ISO 7153-1) and PEEK have been successfully used in the clinical environment for many years. These materials have also been accepted in other systems marketed by Aesculap®, such as the reference device AdTec® (K160393). No new materials have been added.

The materials in the patient contacting Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments conform to the following standards;

- DIN EN ISO 7153-1: Surgical Instruments -- Metallic Materials -- Part 1: Stainless Steel
- ISO 10993-5: Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Cleaning/Sterilization

The Video Assisted Thoracic Surgery (VATS) Instruments are provided non-sterile and are intended to be cleaned and sterilized prior to use. Sterilization of instruments is to be

accomplished by steam autoclave (moist heat) in a standard pre-vacuum cycle. Cleaning and sterilization parameters are provided in the Instructions for Use for the instruments.

The cleaning and sterilization validations provided in this submission conform to the following standards and guidance documents:

- AAMI TIR12:2010 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A guide for Device Manufacturers
- AAMI TIR30:2011 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices
- ANSI/AAMI ST81:2004 (R2010) Sterilization of medical devices – Information to be provided by the manufacturer for processing of resterilizable medical devices.
- FDA Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods *and Labeling* Guidance for Industry and Food and Drug Administration Staff. March 17, 2015

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believe that the Aesculap® Video Assisted Thoracic Surgery (VATS) Instruments are substantially equivalent to the primary predicate, Aesculap® Thoracoscopic Instruments (K944955). As outlined in the comparison table above, the subject device shares similar indications, designs, dimensions, materials, and principals of operation with the primary predicate and reference devices, AdTec® (K160393) and Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments (K120012).

CONCLUSION

The purpose of this 510(k) premarket notification is to gain marketing clearance for the new Video Assisted Thoracic Surgery (VATS) Instruments presented in this submission. The K170683 device instruments are as safe as and equivalent to the primary predicate indications, design / features, components, dimensional ranges, and fundamental scientific technology.