DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 9, 2015

Aegis Surgical Ltd
% Ms. Tammy Carrea
Regulatory Consultant
RegMatters, LLC
113 Grantwood Drive
Holly Springs, NC 27540

Re: K141622
Trade/Device Name: Illuminated Mediastinal Access Port
Regulation Number: 21 CFR 874.4720
Regulation Name: Mediastinoscope and Accessories
Regulatory Class: Class II
Product Code: EWY
Dated: December 7, 2014
Received: December 11, 2014

Dear Ms. Carrea:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat 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)*
K141622

Device Name
Illuminated Mediastinal Access Port

Indications for Use *(Describe)*
The Illuminated Mediastinal Access Port is intended to aid the surgeon in direct visualization of the mediastinum and facilitate the introduction and removal of surgical instruments during surgical procedures.

The Illuminated Mediastinal Access Port is specifically indicated for use in the anterior, superior and middle mediastinum.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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K141622
510(k) Summary
[In accordance with 21CFR 807.92]

1. Submitter / 510(k) Holder

Aegis Surgical, Ltd.
4020 Stirrup Creek Drive – Suite 115
Durham, NC 27703
USA

Contact Person: Tammy B. Carrea
RegMatters, LLC

Date Prepared: December 3, 2014

2. Device Name

Proprietary Name: Illuminated Mediastinal Access Port
Common/Usual Name: Mediastinoscope, Surgical
Classification Name: Mediastinoscope and accessories
Regulation: 874.4720
Classification: Class II
Product Code: EWY

3. Predicate Device(s)

CLASS	MANUFACTURER	510(K) NUMBER	DEVICE NAME/DESCRIPTION
II	Richard Wolf	K971166	Richard Wolf Optical Mediastinoscope

4. Device Description

The Illuminated Mediastinal Access Port is a trocar/cannula system used to provide mediastinal surgical access. The device includes a blunt trocar for dissecting tissue planes. The open cannula provides for direct visualization of the surgical space and includes small notches at the rim to anchor sutures.

The base of the cannula has fiber optic bundles incorporated that may be connected to a fiber optic light cable and an endoscopic light source. This enhances lighting and

visualization within the access device. The device does not include a light source.

The trocar/cannula access device also includes a handle for connection to a support arm. This allows the mediastinoscope to be held in position so that the surgeon can operate using both hands, without holding or re-positioning the mediastinoscope, and to provide stability for the mediastinoscope during operation.

The entire device is disposable, single use and is provided pre-sterilized.

5. Intended Use

The Illuminated Mediastinal Access Port is intended to aid the surgeon in direct visualization of the mediastinum and facilitate the introduction and removal of surgical instruments during surgical procedures.

The Illuminated Mediastinal Access Port is specifically indicated for use in the anterior, superior and middle mediastinum.

6. Comparison of Technological Characteristics with Predicate

The intended use of the Aegis Surgical Illuminated Mediastinal Access Port is the same as the Richard Wolf Optical Mediastinoscope cleared in K971166.

The principles of operation and operational characteristics are the same and include mediastinal access, surgical instrument passage, visualization and illumination, the ability to spread tissue planes and increase surgical access. Both devices are used in a sterile state.

The devices are different in that the Richard Wolf Optical Mediastinoscope is reusable and able to be re-sterilized between uses. The Aegis Surgical Illuminated Mediastinal Access Port is pre-sterilized and single use. Sterilization to an SAL of $1x10^{-6}$ using ethylene oxide was demonstrated via a validated EO cycle.

The two devices are different in that the Richard Wolf Optical Mediastinoscope includes the use of an endoscope while the Aegis Illuminated Mediastinal Access Port provides direct mediastinal visualization but similarly includes illumination by a standard endoscopic light source.

The Illuminated Mediastinal Access Port device and predicate device have differences in the size and shape of the cannula. While both devices provide an open channel for access to the mediastinum and the ability to introduce and utilize surgical instruments through the cannula channel, the predicate device (Richard Wolf Optical Mediastinoscope, K971166) has a narrower channel and instruments are introduced singularly. The Illuminated Mediastinal Access Port device has a wider, trapezoid shaped cannula that allows the clinician to pass multiple instruments through the channel simultaneously. This larger diameter has the ability to improve visualization of the work space and the ability to internally suture as needed.

Another technical difference is the length of the working channel such that the Illuminated Mediastinal Access Device is for use in the anterior, superior and middle mediastinum. Although the two devices have differences in size, the differences do not introduce new or different issues of safety and effectiveness and any possible questions regarding use have been tested using bench or cadaver models to evaluate use and safety.

The handle grip of the Illuminated Mediastinal Access Port device is shorter than that of the predicate device, however, in evaluations of the device in cadaver models, surgeons were able to adequately grip the handle and control the insertion and positioning of the device within the incision. Once positioned, the Illuminated Mediastinal Access Port may be attached to a surgical support arm to provide hands free support and stability during the surgical procedure. More recently marketed versions of the predicate device also include a connection point for connecting to a surgical support arm as displayed in marketing literature.

7. Performance Testing Summary

Like the Richard Wolf Optical Mediastinoscope, the Aegis Surgical Illuminated Mediastinal Access Port was tested to ensure that there was no major deformation of the device when tested under worst case mechanical load conditions.

In addition durability tests were performed to demonstrate that there was no breakage of other parts of the device, specifically the fiber optic bundles were tested and compared to similar medical devices to assure that they do not pull apart under normal conditions of use. The illumination quality was also verified following mechanical tests and simulated use testing.

Biocompatibility studies were performed in accordance with ISO 10993-1:2009 for a limited contact duration device.

Sterilization studies were also performed in accordance with ANSI/AAMI/ISO 11135-2007 "Medical Devices-Validation and routine control of ethylene oxide sterilization" and AAMI TIR 28:2009, "Product adoption and process equivalence for ethylene oxide sterilization" to demonstrate that the Aegis Surgical Illuminated Mediastinal Access Port is able to be ethylene oxide (EO) sterilized to a sterility assurance level of $1x10^{-6}$. Shelf life testing was performed to demonstrate that the sterile packaging maintained a sterile barrier over time and to demonstrate that the product functionality was maintained.

Transit testing was performed to demonstrate that the sterile packaging, corrugate box, and outer shipping container were able to adequately withstand the test conditions required for ISTA 2A distribution standards.

Cadaver testing was performed to establish an appropriate incision size and to evaluate the forces applied to tissue during insertion and extraction. Forces in the lateral and axial directions were also evaluated under worst case conditions to demonstrate that the device does not break or is not damaged.

Lastly the Illuminated Mediastinal Access Port was tested with a compatible light source for spectral irradiance under normal and worst case light output conditions. The testing

compared the output of the light source when connected to a standard fiber optic light cable and when connected to a standard fiber optic light cable in tandem with the Illuminated Mediastinal Access Port. The spectral irradiance of the Illuminated Mediastinal Access Port was considerably less than that of the standard light cable/light source configuration when tested under both typical clinical and worst case light output conditions, indicating that the Illuminated Mediastinal Access Port is safe for use with standard light sources and light cables.

8. Conclusion

The Illuminated Mediastinal Access Port has been shown to be equivalent to the predicate in terms of intended use and operation and the risks of any technological differences have been mitigated through testing.