



Food and Drug Administration
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February 26, 2016

Aegis Surgical Ltd.
Mr. Robert Hefter
Product Development Manager
4020 Stirrup Creek Drive
Suite 115
Durham, NC 27703

Re: K160171

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: January 20, 2016
Received: January 27, 2016

Dear Mr. Hefter:

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,

 Kesia Alexander

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

Indications for Use

510(k) Number (if known)

K160171

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
K160171
Aegis's Illuminated Mediastinal Access Port

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Aegis Surgical, Ltd.
4020 Stirrup Creek Drive – Suite 115
Durham, NC 27703
USA
Phone: (919) 303-6865

Contact Person: Robert P. Hefter

Date Prepared: 02/26/2016

Name of Device and Name/Address of Sponsor

Proprietary Name: Illuminated Mediastinal Access Port

Common/Usual Name: Mediastinoscope, Surgical

Classification Name: Mediastinoscope and accessories

Predicate Devices

Manufacturer	Trade/Model Name	510K Number
Aegis Surgical Ltd.	Illuminated Mediastinal Access Port Model #: 900-01200	K141622

Purpose of the Special 510(k) notice.

The Illuminated Mediastinal Access Port is a modification to previously cleared Aegis' Illuminated Mediastinal Access Port.

Device Description

Illuminated Mediastinal Access Port is a trocar/cannula system used to provide mediastinal surgical access. The device provides open, illuminated surgical access to the mediastinum. The device consists of the following components: Cannula with a working channel, fiber optic bundles, ergonomic handle and blunt tip trocar.

The base of the cannula has fiber optic bundles incorporated that may be connected to a standard endoscopic light source. This enhances lighting and visualization within the access device. The device

does not include a light source. The ergonomic handle provides a secure grip and ease of maneuverability to the user. The device includes a blunt trocar for dissecting tissue planes. The trocar/cannula access device also includes a handle for connection to a support arm. The handle 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 provided pre-sterilized.

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.

Technological Characteristics

The Illuminated Mediastinal Access Port is a trocar/cannula system used to provide surgical access to and direct visualization of the mediastinum to facilitate the introduction and removal of surgical instruments during surgical procedures.

The device includes a blunt trocar for dissecting tissue planes. The open cannula provides for direct visualization of the surgical space.

The base of the cannula has fiber optic bundles incorporated that may be connected to a standard LED endoscopic light source. This enhances lighting and visualization within the access device. The device does not include a fiber optic light cable or a light source.

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

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

Performance Testing

The dimensional/user interface modifications from the predicate device were evaluated by performing a cadaveric usability study. The results of the study concluded that the changes to the device did not adversely affect its safety, effectiveness, or intended use.

Packaging validation and distribution simulation testing were performed to validate seal strength and package integrity.

Substantial Equivalence

Illuminated Mediastinal Access Port has the same intended use and similar indications, principles of operation, and technological characteristics as Aegis previously cleared Illuminated Mediastinal Access Port. The minor differences in the dimensions and design do not raise any new questions of safety or effectiveness. Thus, Illuminated Mediastinal Access Port is substantially equivalent to its predicate devices.