DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 14, 2017

Boston-Biomedical Associates
Lauren Baker
President and CEO
100 Crowley Drive, Suite 216
Marlborough, MA 01752

Re: K170757
Trade/Device Name: Aegis Transit System
Regulation Number: 21 CFR 874.4720
Regulation Name: Mediastinoscope and Accessories
Regulatory Class: Class II
Product Code: EWY
Dated: June 15, 2017
Received: June 16, 2017

Dear Lauren Baker:

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)*
K170757

Device Name
Aegis Transit System

Indications for Use *(Describe)*
The Aegis Transit System is intended to aid the surgeon in direct visualization of the mediastinum and facilitate the introduction and removal of surgical instruments during surgical procedures (e.g., lung, tracheal and esophageal procedures, access to aorta for transcatheter valve procedures and/or thoracic endovascular aortic repair).

The Aegis Transit System 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

1.1 Submitter

Company: Aegis Surgical, Ltd.
4020 Stirrup Creek Drive – Suite 115
Durham, NC 27703
Phone: (508) 351-8632 Ext: 201
Contact Person: Lauren S. Baker, PhD
Date Prepared: March 10, 2017

1.2 Device

Name of Device: Aegis Transit System
Common or Usual Name: Mediastinoscope, Surgical
Classification Name: 21 CFR 874.4720, Mediastinoscope and accessories
Regulatory Class: Class II
Product Code: EWY

1.3 Predicate Device

Name of Device: Aegis Surgical, Ltd.,
Illuminated Mediastinal Access Port
510(k) Number: K141622 and K160171

1.4 Device Description

The proposed Aegis Transit System introduces modifications to the Instructions for Use to propose the use of the two previously cleared Aegis Illuminated Mediastinal Access Ports as a two-step system to improve access and visualization during surgical procedures. The predicate Illuminated Mediastinal Access Ports were cleared under K141622 and K160171. The modifications discussed in this 510(k) submission are listed below:

- The Directions for Use in the IFU have been clarified to address the use of the two previously cleared Illuminated Mediastinal Access Ports as a two-step

system within a single procedure. Please note, the procedural steps that are included in the revised IFU are consistent with the procedural steps that were submitted in K141622 and K160171;

- The indications for use statement has been enhanced to provide examples of the types of procedures in which the transit system may be used;
- The small (dissecting) trocar handle has been revised to incorporate the ergonomic handle cleared with the large (delivery) trocar under K160171;
- The polycarbonate material used in the trocar and cannula of both devices has been changed from industrial grade polycarbonate to medical grade polycarbonate; and
- The packaging has been changed from a nylon/Tyvek heat sealed pouch to a PETG tray with a Tyvek lid.

Both devices are being used in accordance with their cleared indications for use.

1.5 Indications for Use

The Aegis Transit System is intended to aid the surgeon in direct visualization of the mediastinum and facilitate the introduction and removal of surgical instruments during surgical procedures (e.g., lung, tracheal and esophageal procedures, access to aorta for transcatheter valve procedures and/or thoracic endovascular aortic repair). The Aegis Transit System is specifically intended for use in the anterior, superior and middle mediastinum.

1.6 Comparison of Technological Characteristics with the Predicate Device

Please see the Table below.

Table 1-1 Comparison of Technological Characteristics

Characteristic	Aegis Surgical Illuminated Mediastinoscope K141622	Aegis Surgical Illuminated Mediastinoscope K160171	Aegis Transit System Proposed	
			Illuminated Mediastinal Access Port: small (dissecting) trocar	Illuminated Mediastinal Access Port: large (delivery) trocar
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 IMAP is specifically indicated for use in the anterior, superior and middle mediastinum.	Same	The Aegis Transit System is intended to aid the surgeon in direct visualization of the mediastinum and facilitate the introduction and removal of surgical instruments during surgical procedures (e.g., lung, tracheal and esophageal procedures, access to aorta for transcatheter valve procedures and/or thoracic endovascular aortic repair). The IMAP is specifically indicated for use in the anterior, superior and middle mediastinum.	
Principle of Operation	Provide an open channel for access to the mediastinum and the ability to introduce and utilize surgical instruments through the cannula channel and provide access to visualization and illumination	Same	Same	Same
Dimensions, working channel	Working Channel Length: 8 cm (10.5 cm including trocar depth) Outer dimensions of cannula: 3.3 cm x 2.1 cm (w x h)	Working Channel Length: 10 cm (12.5cm including trocar depth) Outer dimensions of cannula: 3.7 cm x 2.9 cm	Same as K141622	Same as K160171
Materials	Cannula body/ Working Channel: Industrial grade Polycarbonate Trocar: Industrial grade Polycarbonate Handle Rod: 303 Stainless steel	Cannula body/Working Channel: Industrial grade Polycarbonate Trocar: Industrial grade Polycarbonate Handle Rod: 303 Stainless steel	Cannula body/Working Channel: Medical grade Polycarbonate Trocar: Medical grade Polycarbonate Handle Rod: 303 Stainless steel	Cannula body/Working Channel: Medical grade Polycarbonate Trocar: Medical grade Polycarbonate

Characteristic	Aegis Surgical Illuminated Mediastinoscope K141622	Aegis Surgical Illuminated Mediastinoscope K160171	Aegis Transit System Proposed	
			Illuminated Mediastinal Access Port: small (dissecting) trocar	Illuminated Mediastinal Access Port: large (delivery) trocar
	Suture Ring: Nylon 6/6 Fiber optic bundles: Encased in silicone with an Ultem connector	rod Cannula Back Handle: Nylon 6/6 Fiber optic bundles: Encased in silicone with an Ultem connector	rod Cannula Back Handle: Nylon 6/6 Fiber optic bundles: Encased in silicone with an Ultem connector	Handle Rod: 303 Stainless steel rod Cannula Back Handle: Nylon 6/6 Fiber optic bundles: Encased in silicone with an Ultem connector
Shelf Life	3 months	3 months	3 years	3 years
Access	Open access channel to the mediastinum to pass surgical instruments. Adequate width incorporated within the cannula's channel dimensions.	Same	Same	Same
Visualization	Direct visualization through open channel cannula	Same	Same	Same
Illumination	Yes	Same	Same	Same
Sterilization	EO, Single use, pre-sterilized	Same	Same	Same
Packaging	Nylon/Tyvek heat sealed pouch.	Same	PETG Tray with Tyvek Lid	PETG Tray with Tyvek Lid
Surgical Support Arm Connection	Yes	Yes	Yes	Yes

1.7 Performance Data

No new bench testing was required for an assessment of substantial equivalence; the bench testing submitted and reviewed under K141622 and K160171 is applicable to the proposed Aegis Transit System. The only design change was made to the small (dissecting) trocar, which was modified to incorporate the ergonomic handle that was cleared with the large (delivery) trocar in K160171. Both this change and the proposed labeling change have no impact on the intended use of the device. Therefore, the testing completed in support of the ergonomic handle for the large (delivery) trocar (K160171) is adequate to support the use of the ergonomic handle in the small (dissecting) trocar.

1.8 Conclusions

The proposed Aegis Transit System utilizes the two predicate devices, the Illuminated Mediastinal Access Ports, within their cleared intended use. The Aegis Transit System may be found to be substantially equivalent to the predicate Illuminated Mediastinal Access Ports.