K082174

Asthmatx®

OCT 20 2008

7.0 510(k) Summary

Applicant: Asthmatx, Inc.
888 Ross Drive, Suite 100
Sunnyvale, CA 94089
T: 408.419.0100
F: 408.419.0101

Contact: Carter Navarro
Manager, Regulatory Affairs
T: 408.419.0105
F: 408.419.0101
E: cnavarro@asthmatx.com

Date: September 30, 2008

Trade name: Y-Adapter
Common name: Y-Adapter

Classification

Classification Name: Bronchoscope accessory
Regulation Number: 21 CFR 874.4680
Product Code: KTI
Class: II
Classification Panel: Ear Nose & Throat

Predicate Device: Olympus Single-use Biopsy Valve
(Component of the Olympus EVIS EXERA II 180 System, cleared via K061313 on August 30, 2006)

Description
The Y-Adapter is a device that provides a passage through which fluids can be delivered via the instrument channel of a bronchoscope without requiring the removal of bronchoscopic accessories from the instrument channel. The Y-Adapter attaches to the instrument channel port, and provides two ports to the channel: one for use with a catheter or other bronchoscopic accessory and one for use in the delivery of fluids.

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Intended Use
The Y-Adapter is intended for use in the delivery of fluids via the instrument channel of a bronchoscope.

Technological Characteristics
The Y-Adapter provides two ports through which the instrument channel can be accessed. The fluid delivery interface of each port of the Y-Adapter is comparable to that of the predicate device.

The Y-Adapter is manufactured from polyethylene and silicone rubber. Both materials in the Y-Adapter are widely used in medical applications and will be formulated to comply with the FDA-recognized biocompatibility standard ISO 10993-1:2003. The predicate device is manufactured from materials that are not specified in the available labeling.

Performance Verification
The Y-Adapter will conform to the requirements of the following guidance documents and FDA-recognized standards prior to marketing of the device:

- Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995 (G95-1)
- Updated 510(k) Sterility Review Guidance, August 30, 2002 (K90-1)
- ISO 10993-1:2003 – Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 11137-1:2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 11607-1:2006 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

In addition, the following design and functional characteristics will be verified prior to marketing of the Y-Adapter:

- Physical dimensions
- Compatibility with common bronchoscopes
- Compatibility with common fluids (e.g., saline, lidocaine solution)
- Maintenance of vacuum
- Prevention of leaks

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Conclusion

The intended use, technological characteristics, and planned performance verification and conformance to recognized standards of the Y-Adapter indicate that it is as safe and effective as, and is substantially equivalent to, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asthmatx, Inc.
c/o Carter Navarro
888 Ross Drive
Sunnyvale, CA 94089

OCT 20 2008

Re: K082174
Trade/Device Name: Y-Adapter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: October 1, 2008
Received: October 2, 2008

Dear Mr. Navarro:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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

6.0 Indications for Use

510(k) Number (if known): K082174

Device Name: Y-Adapter

Indications for Use:

- For use in the delivery of fluids via the instrument channel of a bronchoscope.
- For single use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Baker

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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