K091768

510(k) Summary

Date Prepared (21 CFR 807.92(a)(1): June 6, 2009

AUG 0 8 2009

Owner's Name (21 CFR 807.92(a)(1):

Vision-Sciences, Inc.
Address: 40 Ramland Road South
Orangeburg, NY 10962
Telephone Number: (845) 365-0600
Fax Number: (845) 365-0620
Contact Person: Lillian Quintero; Director QA/RA

Trade Name, Common Name, Classification (21 CFR 807.92(a)(2))

Subject Device Name: BRS-5000 Video Bronchoscope and BV Slide-On® EndoSheath® Systems with Digital Video Processor

Common/Usual Name: Flexible Video Bronchoscope with Sheath and Video Processor

Product Codes: EOQ
FDA Regulations: 21 CFR 874.4680
Device Classification: Class II

Predicate Device Names (21 CFR 807.92(a)(3))

K072088 Flexible Trans-Nasal Esophagoscope with Digital Video Processor and Disposable EndoSheath® Systems

K021344 Flexible Fiberoptic Bronchoscope with Disposable EndoSheath

Intubation of the airways for Bronchoscopes has received FDA marketing clearance in the following 510(k) Premarket Notifications:

K981543 Olympus Tracheal Intubation Fiberscope
K082720 Olympus Tracheal Intubation Fibervideoscope

Common/Usual Name: Flexible fiberoptic endoscopes with sheaths and accessories
Product Codes: EOB, EOQ
FDA Regulations: 21 CFR 874.4760
Device Classification: Class II
Premarket Notification: K050972 / K040984 / K024095 / K942265

Device Description
The VSI flexible endoscopes are flexible endoscopes with connections to a video processor and display monitor. The EndoSheath® Systems are sterile, single-use protective sheath systems, with or without a working channel, that are intended to cover the entire insertion tube of the videoscope. The digital video processors are used with the flexible videoscopes for image visualization and capture.

Intended Use
The bronchoscope and EndoSheath® Technology are designed to be used for upper airway management: including endoscopic treatment, diagnosis, and intubation of the airways.

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Technological Characteristics

Vision Sciences believes that the subject device is substantially equivalent to the Vision Sciences' predicate devices. The subject device has very similar material composition, construction and working dimensions; and identical viewing direction, image size, bending, re-processing/sterilization method and working dimensions as the predicate. In addition, the subject device uses the same video processor as Vision Sciences other videoscopes.

Performance Testing

The subject device has been subjected to and passed electrical safety, thermal, and ECM testing requirements. The patient contact materials in the endoscope are identical to the materials used in predicate device (Vision Sciences' TNE-5000 (K072088)).

Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the VSI flexible video endoscopes with digital video processors and disposable EndoSheath® Systems have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 3 2009

Vision Sciences, Inc
c/o Stacie Geffner-Atiya
40 Ramland Road, South
Orangeburg, NY 10962

Re: K091768
Trade/Device Name: Flexible Video Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 11, 2009
Received: June 16, 2009

Dear Ms. Geffner-Atiya:

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.

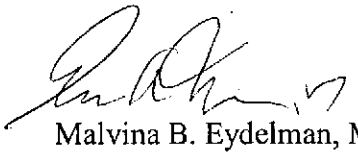
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K091768

Device Name: Video Bronchoscope with Digital Video Processor and BV Slide-On® EndoSheath® Systems

Indications for Use: The bronchoscope and EndoSheath® Technology are designed to be used for upper airway management: including endoscopic treatment, diagnosis, and intubation of the airways.

The digital video processor is intended for use with the VSI flexible video scope.

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen J Baker

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

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