K052452

SEP 2 1 2005

510(k) SUMMARY

VISERA Rhino-Laryngovideoscope Olympus ENF type VT

August 26, 2005

1 General Information

■ Applicant	Olympus Medical Systems Corp. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No.: 8010047
■ Official Correspondent	Laura Storms-Tyler Executive Director, Regulatory Affairs & Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058, USA Phone: 631-844-5688 FAX: 631-844-5554 Email:Laura.storms-tyler@olympus.com Establishment Registration No.: 2429304
■ Manufacturer	Aizu Olympus Co., Ltd. 500 Aza-Muranishi, Ooaza-Iidera, Monden-cho, Aizuwakamatsu-shi, Fukushima, Japan 965-8520 Establishment Registration No.: 9610595

2 Device Identification

Device Name	VISERA Rhino-Laryngovideoscope Olympus ENF type VT
■ Common Name	Nasopharyngoscope
■ Regulation No:	21 CFR 874.4760
■ Regulation Name:	Nasopharyngoscope (flexible or rigid) and accessories
■ Regulatory Class:	II
■ Product Code:	EOB
■ Prescription Status:	Prescription device
■ Performance Standards:	None established under Section 514 of FDCA.

K05 2452

3 Predicate Device Information

■ Device Name	Rhino-Laryngofiberscope Olympus XENF-TP
■ 510(k) No:	K013591
■ Decision Date:	12/26/2001

4 Device Description

The VISERA Rhino-Laryngovideoscope Olympus ENF type VT, hereafter referred to as ENF-VT, is a flexible video endoscope used for endoscopic diagnosis and treatment within the nasal and nasopharyngeal lumens.

The modifications that were made are:
- Field of view is wider.
- Instrument channel inner diameter is smaller.
- Optical system is changed to a CCD based system, allowing endoscopic image display on a video monitor.
- Improved resolution
- The subject device is not compatible with a miniature light source, whereas the predicate device is

5 Intended Use

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the nasal and nasopharyngeal lumens.

This intended use is identical to the predicate device, the Rhino-Laryngofiberscope Olympus XENF-TP.

6 Conclusion

The VISERA Rhino-Laryngovideoscope Olympus ENF type VT has the following similarities to the predicate device:
- The same intended use.
- The same operating principle except for the optical system.
- The same reprocessing method.
- The same basic endoscope design except for the optical system.
- The same patient contacting materials as for the Olympus predicate devices.

In summary, the ENF-VT described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Olympus Medical Systems Corporation
c/o Laura Storms-Tyler
Executive Director
Olympus America, Inc.
Regulatory Affairs and quality Assurance
Two Corporate Center Drive
PO Box 9058
Melville, NY 11747-9058

Re: K052452
Trade/Device Name: VISERA Rhino-Laryngovideoscope Olympus ENF type VT
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: September 1, 2005
Received: September 7, 2005

Dear Ms. Storms-Tyler:

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 Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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):

Device Name: VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF TYPE VT

Indications For Use:

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the nasal and nasopharyngeal lumens.

Prescription Use √ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052452