SMDA 510(k) SUMMARY

EVIS EXERA Bronchovideoscope Olympus XBF-1T160Y3AC, XBF-160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

1. GENERAL INFORMATION

Applicant	Olympus Corporation 34-3 Hirai Hinode-machi, Nishitama-gun, Tokyo, 190-0182, Japan Establishment Registration No.: 3003637092
Submission Correspondent	Akiko Fukagawa Olympus Corporation 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Phone: +81-426-2891 Fax: +81-426-3174 E-mail: akiko_fukagawa@ot.olympus.co.jp Establishment Registration No.: 8010047
Official Correspondent	Tina Steffanie-Oak Associate Manager, Regulatory Affairs/Clinical Monitor Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058 Phone: 631-844-5477 Fax: 631-844-5554 Establishment Registration No.: 2429304

2. Device Identification

Trade Name:	EVIS EXERA Bronchovideoscope Olympus XBF-160Y3AC, XBF-1T160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment
Common Name:	Bronchoscope
Regulation Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Class:	II
Product Code:	EOQ

3. Predicate Device

Predicate Device Name	Manufacturer	510(k) Number
EVIS EXERA Bronchovideoscope Olympus BF type 160	Olympus Corporation	K023984
EVIS EXERA Bronchovideoscope Olympus BF type 1T160	Olympus Corporation	K023984
Olympus Sterilization Trays	Olympus Winter & Ibe GMBH	K033222

4. Device Description

The subject devices, Olympus EVIS EXERA Bronchovideoscope XBF-160Y3AC, XBF-1T160Y3AC, and XBF-Q160Y2AC are identical to the predicate devices, BF-160 and BF-1T160, in intended use. These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree. As for the device specifications, they are basically identical to the BF-160 and BF-1T160 with the exception that the subject devices are now compatible with steam sterilization (autoclave) in addition to ETO gas sterilization. The XBF-Q160Y2AC is loaded with higher pixels in the CCD compared to the predicate device, BF-160. The increase of the number of pixels has contributed to the expansion of image size. However, the resolution at optimum working distance of the XBF-Q160Y2AC is basically the same as that of the predicate device. Therefore, optical performance of the XBF-Q160Y2AC before and after clinical use is identical to the predicate device.

In addition to the above scopes, this submission also includes the following devices:

XMAJ-178 (Sterilization Tray)
MAJ-1214 (Water-resistant Cap)
FB-52C-1 Biopsy Forceps
FG-36D Grasping Forceps
IE-2P Magnetic Extractor
NM-8L-1 Injector
NM-9L-1 Injector
M1-1G Measuring Device
M2-1C Measuring Device
M2-2C Measuring Device

5. Intended Use of the device

EVIS EXERA Bronchovideoscope

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Accessories to the EVIS EXERA Bronchovideoscope

XMAJ-178 (Sterilization Tray)
The XMAJ-178 is a sterilization tray intended for use in medical facilities to accommodate the Olympus autoclavable Bronchovideoscopes during autoclaving.

MAJ-1214 (Water-resistant Cap)
The MAJ-1214 is attached to the electrical connector on the endoscope to protect the connector from water penetration during reprocessing.

FB-52C-1 (Biopsy Forceps)
The FB-52C-1 has been designed to be used with an Olympus endoscope to collect tissue within the thoracic and abdominal cavities and the airways and tracheobrochial tree.

FG-36D (Grasping Forceps)
This instrument has been designed to be used with Olympus endoscopes to retrieve foreign bodies, caluculi or tissue specimens from the digestive tract, urinary tract, female reproductive tract and respiratory organs.

IE-2P (Magnetic Extractor)
The Olympus IE-2P magnetic Extractor has been specially designed to be used within the airways and tracheobrochial tree.

NM-8L-1/NM-9L-1 (Injector)
These instruments have been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection within the thoracic and abdominal cavities and the airways and tracheobrochial tree.

M1-1C/M2-1C/M2-2C (Measuring Device)
These measuring devices have been designed for measuring leisions within the thoracic and abdominal cavities and the airways and tracheobochial tree.

6. Comparison of Technological Characteristics

Below is the comparison table between the subject devices and predicate device.

Specifications	Subject Device XBF-160Y3AC	Subject Device XBF-1T160Y3AC	Subject Device XBF-Q160Y2AC	Predicate Device BF-160 (K023984)
Reprocessing	ETO/Autoclaving	ETO/Autoclaving	ETO/Autoclaving	ETO
Distal end Outer Diameter	ϕ 4.9 mm	ϕ 5.9 mm	ϕ 5.5 mm	ϕ 5.3 mm
Insertion Tube Outer Diameter	ϕ 4.9 mm	ϕ 6.0 mm	ϕ 5.3 mm	ϕ 5.2 mm
Inner Channel Diameter	ϕ 2.0 mm	ϕ 2.8 mm*	ϕ 2.0 mm	ϕ 2.0 mm

*Inner Channel Diameter of XBF-1T160Y3AC is identical to that of the other predicate device, BF-1T160.

7. Materials

Biocompatibility testing was performed in accordance with Japan's Ministry of Health and Welfare notification "GUIDELINES FOR BASIC BIOLOGICAL EVALUATION OF MEDICAL DEVICES" (issued on June 27 1995), YAKKI No.99.

8. Conclusion

When compared to the predicate device, XBF-160Y3AC, XBF-1T160Y3AC and XBF-Q160Y2AC do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety and effectiveness. Therefore, clinical data is not necessary for its evaluation of safety and efficacy.