September 5, 2018

Sonoscape Medical Corp.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K173921
Trade/Device Name: HD-500 Video Endoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NWB, FDF, FDS
Dated: July 13, 2018
Received: July 24, 2018

Dear Diana Hong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K173921

Device Name
HD-500 Video Endoscope System

Indications for Use *(Describe)*

HD-500 Video Endoscope System

The HD-500 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopies examination, diagnosis and treatment of the disease of the upper and lower gastrointestinal tract.

HDL-500 Series Light Source, HDL-500E, HDL-500X

The HDL-500 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.

HD-500 Series Image Processor, HD-500, HD-500S, HD-330Plus

The HD-500 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and video recording.

EG-500 Series Video Gastroscope, EG-500, EG-500L

The EG-500 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).

EC-500 Series Video Colonoscope, EC-500, EC-500T, EC-500L, EC-500L/T

The EC-500 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment).

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K173921

1. Date of Preparation: 11/30/2017

2. Sponsor Identification

**SONOSCAPE MEDICAL CORP.**
4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China

Establishment Registration Number: 3004705634

Contact Person: Toki Wu
Position: Regulatory Affairs Manager
Tel: 0755-26722890
Fax: 0755-26722850
Email: ra@sonoscape.net

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 001-3609253199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: HD-500 Video Endoscope System
Common Name: Endoscopic Video Imaging System
Components and Component Models:

| | |
|---|---|
| EG-500 Series Video Gastroscope: | EG-500, EG-500L |
| EC-500 Series Video Colonoscope: | EC-500, EC-500T, EC-500L, EC-500L/T |
| HD-500 Series Image Processor: | HD-500, HD-500S, HD-330Plus |
| HDL-500 Series Light Source: | HDL-500E, HDL-500X |

Regulatory Information

Classification Name: Endoscope and accessories
Classification: II
Product Code: NWB, FDF and FDS
Regulation Number: 21 CFR 876.1500 Endoscope and accessories
Review Panel: Gastroenterology/Urology

Intended Use Statement:

HD-500 Video Endoscope System

The HD-500 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopies examination, diagnosis and treatment of the disease of the upper and lower gastrointestinal tract.

EG-500 Series Video Gastroscope, EG-500, EG-500L

The EG-500 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).

EC-500 Series Video Colonoscope, EC-500, EC-500T, EC-500L, EC-500L/T

The EC-500 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment).

HD-500 Series Image Processor, HD-500, HD-500S, HD-330Plus

The HD-500 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and video recording.

HDL-500 Series Light Source, HDL-500E, HDL-500X

The HDL-500 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.

Device Description

The proposed device, HD-500 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices.

HD-500 Video Endoscope System can be offered in several configurations with the options of different models of primary components

The EG-500 Series Video Gastroscope/ EC-500 Series Video Colonoscope is the hand-held, direct-viewing flexible endoscope used for endoscopy and endoscopic surgery within the upper and lower gastrointestinal tract.

The HD-500 Series Image Processor is a video processing system which is designed to be used with endoscopes, light source, monitor of the proposed system. Apart from the image processing functions, it also provides power supply for the endoscopes.

The HDL-500 Series Light Source provides illumination for endoscopic diagnosis, treatment and video observation.

5. Identification of Predicate Device

510(k) Number: K100584
Product Name: EVIS EXERA II 180 System
Primary components and Component Models:

| | |
|---|---|
| EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE | OLYMPUS GIF TYPE Q180,<br>OLYMPUS GIF TYPE H180 |
| EVIS EXERA II COLONOVIDEOSCOPE | OLYMPUS CF TYPE Q180AL<br>OLYMPUS CF TYPE Q180AI |
| EVIS EXERA II VIDEO SYSTEM CENTER | OLYMPUS CV-180 |
| EVIS EXERA II XENON LIGHT SOURCE | OLYMPUS CLV-180 |

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance, including the US National Differences
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests

- IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 8600-1:2015 Endoscopes--Medical endoscopes and endotherapy devices - part 1: General requirements
- ISO 8600-7:2012 Endoscopes --Medical endoscopes and endotherapy devices - part 7: Basic requirements for medical endoscopes of water-resistant type
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Optical performance testing

The following testing was conducted to evaluate the optical performance characteristics for each endoscopic system mode.

- Photobiological safety
- Resolution (test results comparison between the proposed device and predicate device)
- Depth of field (test results comparison between the proposed device and predicate device)
- Optical magnification and distortion (test results comparison between the proposed device and predicate device)
- Image intensity uniformity (test results comparison between the proposed device and predicate device)

Physical/functional performance testing

The endoscope performance test was conducted to evaluate the ability of proposed endoscope to maintain the maximum angulation/deflection when in use, the physical/functional performance of the proposed device, including a) Appearance visual inspection and handle strength inspection, b) Image function visual inspection, c) Sealing performance, and d) Maximum bending angle measurement and body model testing.

Imaging performance testing

The imaging performance testing was conducted to demonstrate that the imaging quality of the proposed device is still in a better condition when the device is over its lifetime of clinical use. The degradations of imaging performance are very little which will not affect the normal use of the endoscope.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

The whole system and components of the proposed device is basically identical to its predicate device in indication for use, and similar in specification. Comparisons between the proposed device and predicate device are shown in Table 1 to Table 6.

Table 1 General Comparison
Proposed device: HD-500 Video Endoscope System
Predicate device: EVIS EXERA II 180 SYSTEM

| ITEM | Proposed Device | Predicate Device<br>K100584 |
|---|---|---|
| Product Code | NWB, FDF and FDS | NWB, FDF and FDS |
| Regulation Number | 21 CFR 876.1500 | 21 CFR 876.1500 |
| Class | II | II |
| Indications for Use<br>*(SE Analysis 1)* | HD-500 Video Endoscope System<br>The HD-500 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopies examination, diagnosis and treatment of the disease of the upper and lower gastrointestinal tract. | / |
| | HDL-500 Series Light Source, HDL-500E, HDL-500X<br>The HDL-500 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment. | EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180<br>This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation. |
| | HD-500 Series Image Processor, HD-500, HD-500S, HD-330Plus<br>The HD-500 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and video recording. | EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180<br>This video system center has been designed to be used with OLYMPUS camera heads, endoscopes, light sources, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation. |
| | EG-500 Series Video Gastroscope, EG-500, EG-500L | EVIS EXERA II GASTROINTESTINAL |

| | | |
|---|---|---|
| | The EG-500 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum). | VIDEOSCOPE OLYMPUS GIF TYPE Q180, OLYMPUS GIF TYPE H180<br>These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy) and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum). |
| | <u>EC-500 Series Video Colonoscope, EC-500, EC-500T, EC-500L, EC-500L/T</u><br>The EC-500 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment). | EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL. OLYMPUS CF TYPE Q180AI.<br>These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve). |
| Configuration (primary components) | Light Source | Light Source |
| | Image processor | Image processor |
| | Video Gastroscope | Video Gastroscope |
| | Video Colonoscope | Video Colonoscope |
| | Accessories and peripheral devices | Accessories and peripheral devices |

<u>SE Analysis 1-Indications for Use</u>

The indications for use of proposed device is summarized for the whole video endoscope system and the primary components, the indications for use of predicate device is only summarized for the primary components. It is only the different expressions on indications for use, actually the proposed device and the predicate device have the same primary components, each of the primary component has the same intended use. Therefore, this item is considered as substantial equivalence.

Table 2 Specifications Comparison of Image Processor

Proposed device: HD-500 Series Image Processor (HD-500, HD-500S, HD-330Plus)

Predicate device: EVIS EXERA II VIDEO SYSTEM CENTER (OLYMPUS CV-180)

| ITEM | | Proposed Device | | | Predicate Device |
|---|---|---|---|---|---|
| Model | | HD-330Plus | HD-500 | HD-500S | OLYMPUS CV-180 |
| Power supply | | 100-240V AC, 50/60Hz | 100-240V AC, 50/60Hz | 100-240V AC, 50/60Hz | 100-240V AC, 50/60Hz |
| Over-current protection | | Fuse type | Fuse type | Fuse type | Fuse type |
| Input current *(SE Analysis 2)* | | 160VA | 160VA | 160VA | 150VA |
| Size *(SE Analysis 3)* | | 370(W)×124(H)×455(D)mm | 370(W)×124(H)×455(D)mm | 370(W)×124(H)×455(D)mm | 383(W)x162(H)x536(D)mm |
| Weight *(SE Analysis 3)* | | 9.5 Kg | 9.5 Kg | 9.5 Kg | 15.4kg |
| compatible endoscope | | Videoscope | Videoscope | Videoscope | Fiber/rigid scope with camera head<br><br>Videoscope |
| Observation | Video signal output *(SE Analysis 4)* | DVI:1<br>VGA:1<br>Y/C:1<br>VBS:1 | DVI:1<br>VGA:1<br>SDI:1<br>Y/C:1<br>VBS:1 | DVI:1<br>VGA:1<br>SDI:1<br>Y/C:1<br>VBS:1 | RGB:3<br>Y/C:4<br>VBS:4<br>HDTV:1 |
| | Auto white balance | Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically | Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically | Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically | Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically |

| | | | | | |
|---|---|---|---|---|---|
| | Standard color char output | Color bar image | Color bar image | Color bar image | Color bar image |
| | Color tone adjustment | R: ±8 steps B:±8 steps<br>Chroma:±8 steps | R: ±8 steps B:±8 steps<br>Chroma:±8 steps | R: ±8 steps B:±8 steps<br>Chroma:±8 steps | R:±8 steps B:±8 steps<br>Chroma:±8 steps |
| | Automatic gain control | Provided | Provided | Provided | Provided |
| | Image enhancement *(SE Analysis 5)* | Edge enhancement: [1][2][3] 3-mode selectable and each mode have 9 levels adjustable by the user<br>Structure enhancement: [1][2][3] 3-mode selectable and each mode have 9 levels adjustable by the user<br>Contrast enhancement: [low][med][high] 3 levels available<br>Color enhancement: [1][2][3] 3-mode selectable and each mode have 9 levels adjustable by the user | | | Edge enhancement: [off][low][med][high] 4 levels available<br>structure enhancement: [off][low][med][high] 4 levels available |
| | IRIS mode selection *(SE Analysis 6)* | Peak/AVE/Auto photometry mode | Peak/AVE/Auto photometry mode | Peak/AVE/Auto photometry mode | Peak/Auto photometry mode |
| | Zoom *(SE Analysis 7)* | ×1.4 /×1.6/×1.8 | ×1.4 /×1.6/×1.8 | ×1.4 /×1.6/×1.8 | ×1/×1.2/×1.5 3-mode |
| | Imaging modes *(SE Analysis 8)* | Common observation mode;<br>VIST observation mode | Common observation mode;<br>VIST observation mode | Common observation mode;<br>VIST observation mode | White-light imaging mode<br>Narrow Band Imaging (NBI) modes |
| Foot switch connector | | Provided | Provided | Provided | Provided |
| record to memory card | | Provided | Provided | Provided | Provided |

SE Analysis 2-Input Current

The input current of proposed devices is similar as that of the predicate device. In addition, the input current proposed device complies with IEC 60601-1 standard. Therefore, this difference on input current is considered not affect the safety and effectiveness of the proposed device.

SE Analysis 3-Size and Weight

The physical specifications are different between the proposed devices and predicate device; the difference on physical specification will not affect the safety and effectiveness of the proposed device.

SE Analysis 4-Video Signal Output

The types of video signal output are different between the proposed devices and predicate device; the difference on video signal output will not affect the safety and effectiveness of the proposed device based on the following reasons:

a. Both the proposed system and predicate system are the high-definition endoscope system; they all have the standard -definition interface and high-definition interface. The proposed system has more interfaces than that of the predicate system, these interfaces improve the system's versatility.
b. Standard -definition interface: Y/C interface and VBC interface belong to the standard -definition interface.
c. High-definition interface: DVI interface is substantially equivalent to the HDTV interface; VGA interface is substantially equivalent to the RGB interface.
d. SDI interface belongs to the direct output interface. The display of the monitor can be switched to SDI signal output in case of the image processor suddenly doesn't work or the system suddenly crashes.

SE Analysis 5- Image enhancement

The proposed devices provide more selection about the image enhancement; it will offer the physician more selection to adjust the observation. This difference will not affect the safety and effectiveness of the proposed device.

SE Analysis 6- IRIS mode selection

The proposed devices provide more selection about the IRIS mode; it will offer the physician more selection to adjust the observation. This difference will not affect the safety and effectiveness of the proposed device.

SE Analysis 7- Zoom

The zoom of image processor is similar as that of the predicate image processor. This difference will not affect the safety and effectiveness of the proposed device.

SE Analysis 8- Imaging modes

The predicate device has both white-light imaging and Narrow Band Imaging (NBI) modes. The NBI mode selectively processes green and blue light images by filtering the white light spectrum with an optical filter, and thus enhances visualization of superficial vasculature. The HDL-500X light source also has two modes, the common observation and the VIST observation modes. In the VIST observation mode, a dedicated light filter is inserted into the light path to filter out the light of a specific color, thereby achieving exclusiveness. The common observation mode of proposed device is same as the white-light imaging mode of the predicate device. Both VIST technology (proposed device) and NBI technology (predicate device) are special light imaging technologies taking advantage of the difference of the extinction spectra between mucosal vessels and mucosa. Both of them utilize optical filtering and digital image processing to enhance the visibility of mucosal vessels. Although there are differences on specific optical and digital filtering parameters, leading to slight difference in the color of the corresponding images, they are not the essential differences. VIST can still achieve the same clinical application purposes as NBI does. Therefore, the VIST observation mode of proposed device is substantially equivalent to the NBI imaging mode of the predicate device.

Table 3 Specifications Comparison of Video Gastroscope

Proposed device: EG-500 Series Video Gastroscope

Predicate device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS

| ITEM | Proposed device | | Predicate device | |
|---|---|---|---|---|
| Model | EG-500 | EG-500L | GIF-Q180 | GIF-H180 |
| Field of view | 140° | 140° | 140° | 140° |
| Depth of focus | 3-100mm | 3-100mm | 3-100mm | 2-100mm |
| Front view | 0° | 0° | 0° | \ |
| Sensor type *(SE Analysis 9)* | color CMOS | color CMOS | color CCD | color CCD |
| Distal end outer diameter *(SE Analysis 10)* | 9.3mm | 9.8mm | 8.8mm | 9.8mm |
| Insertion section outer diameter *(SE Analysis 10)* | 9.3mm | 9.8mm | 8.8mm | 9.8mm |
| Bend angle | UP:210°<br>DOWN:90°<br>RIGHT:100°<br>LEFT:100° | UP:210°<br>DOWN:90°<br>RIGHT:100°<br>LEFT:100° | UP:210°<br>DOWN:90°<br>RIGHT:100°<br>LEFT: 100° | UP:210°<br>DOWN:90°<br>RIGHT:100°<br>LEFT: 100° |
| Insertion section length *(SE Analysis 11)* | 1050mm | 1050mm | 1030mm | 1030mm |
| Biopsy channel inner diameter *(SE Analysis 10)* | 2.8mm | 3.2mm | 2.8mm | 2.8mm |

SE Analysis 9- Sensor type

Although the CMOS sensor and CCD sensor have different photosensitive logic, but both they can provide high quality image. And the CMOS sensor has been commonly used in the endoscope systems. Therefore, this difference on sensor type does not affect the safety and effectiveness of the proposed device.

SE Analysis 10- Diameters

The Distal end outer diameter, Insertion section outer diameter and Biopsy channel inner diameter of proposed device are similar as those of the predicate device. Those diameters meet the industrial standard. Therefore, this item is considered as substantial equivalence.

SE Analysis 11- Insertion section length

The insertion section length of proposed device is similar as that of the predicate device. Therefore this item is considered as substantial equivalence.

Table 4 Specifications Comparison of Video Colonoscope

Proposed device: EC-500 Series Video Colonoscope

Predicate device: EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE

| ITEM | Proposed device | | | | Predicate device |
|---|---|---|---|---|---|
| Model | EC-500 | EC-500T | EC-500L | EC-500L/T | CF-Q180AL/ CF-Q180AI |
| Field of view *(SE Analysis 12)* | 140° | 140° | 140° | 140° | 170° |
| Depth of focus | 3-100mm | 3-100mm | 3-100mm | 3-100mm | 3-100mm |
| Front view | 0° | 0° | 0° | 0° | 0° |
| Sensor type *(SE Analysis 9)* | color CMOS | color CMOS | color CMOS | color CMOS | color CCD |
| Distal end outer diameter *(SE Analysis 10)* | 12mm | 12mm | 12.9mm | 12.9mm | 13.2mm |
| Insertion section outer diameter *(SE Analysis 10)* | 12.5mm | 12.5mm | 12.9mm | 12.9mm | 12.8mm |
| Bend angle | UP:180°<br>DOWN:180°<br>RIGHT:160°<br>LEFT: 160° | UP:180°<br>DOWN:180°<br>RIGHT:160°<br>LEFT: 160° | UP:180°<br>DOWN:180°<br>RIGHT:160°<br>LEFT: 160° | UP:180°<br>DOWN:180°<br>RIGHT:160°<br>LEFT: 160° | UP:180°<br>DOWN:180°<br>RIGHT:160°<br>LEFT: 160° |
| Insertion section length *(SE Analysis 11)* | 1350mm | 1700mm | 1350mm | 1700mm | 1680mm |
| Biopsy channel inner diameter *(SE Analysis 10)* | 3.8mm | 3.8mm | 4.2mm | 4.2mm | 3.7mm |

SE Analysis 12- Field of view

Although the field of view of the proposed video colonoscope is different than that of the predicate video colonoscope, the field of view of the proposed video colonoscope meets the requirements of ISO 8600-1 standard. Therefore, this difference on field of view does not affect the safety and effectiveness of the proposed device.

Table 5 Specifications Comparison of Light Source

Proposed device: HDL-500E Light Source/ HDL-500X Light Source

Predicate device: EVIS EXERA II XENON LIGHT SOURCE (OLYMPUS CLV-180)

| ITEM | HDL-500E Light Source | HDL-500X Light Source | Predicate device |
|---|---|---|---|
| Power supply *(SE Analysis 13)* | AC 100-240V<br>50Hz/60Hz | AC 100-240V<br>50Hz/60Hz | AC 100-120V,<br>50/60HZ ±1Hz |
| Over-current protection | Fuse type | Fuse type | Fuse type |
| Input current *(SE Analysis 14)* | 160VA | 500VA | 500VA |
| Examination lamp *(SE Analysis 15)* | 50W LED | 300W xenon lamp | 300W Xenon lamp |
| Average lamp life *(SE Analysis 16)* | 50000 hours | 500 hours | Approximately 500 hours of continuous use |
| Emergency lamp *(SE Analysis 15)* | 14W LED | 12V 60W halogen lamp | 12V 35W Halogen lamp |
| Average emergency lamp life *(SE Analysis 17)* | 50000 hours | 4000 hours | Approximately 500 hours |
| Brightness control | Automatic and manual | Automatic and manual | Automatic and manual |
| Automatic exposure *(SE Analysis 18)* | 19 steps | 19 steps | 17 steps |
| Air feeding | 4 levels available (off, low, mid, high) | 4 levels available (off, low, mid, high) | 4 levels available (off, low, mid, high) |
| System connector | Provided | Provided | Provided |
| Foot switch connector | Provided | Provided | Provided |
| CV connector | Provided | Provided | Provided |

SE Analysis 13-Power supply

Although the power supply of proposed light source is different from that of the predicate device, the electrical safety testing of proposed device demonstrates that the power supply of the proposed device meets the requirements of IEC 60601-1 Standard. Therefore, this difference on power supply does not affect the safety and effectiveness of the proposed device.

SE Analysis 14-Input current

The input current of proposed HDL-500X Light Source is same as that of the predicate device. While the input current of proposed HDL-500E Light Source is different from that of the predicate device, the input current of proposed HDL-500E Light Source complies with IEC 60601-1 standard). Therefore this difference on input current is considered not affect the safety and effectiveness of the proposed device.

SE Analysis 15- Examination lamp and Emergency lamp

The proposed HDL-500X Light Source has the same light source as that of the predicate device. The proposed HDL-500E has different light source from that of the predicate device. The LED light source of HDL-500E is also a common light source used in endoscope system, therefore this difference on examination lamp and emergency lamp does not affect the safety and effectiveness of the proposed device.

SE Analysis 16- Average lamp life

The proposed HDL-500X Light Source has the same lamp life as that of the predicate device. The proposed HDL-500E has longer lamp life than that of the predicate device. The LED light source of HDL-500E is also a common light source used in endoscope system. Therefore, this difference on lamp life does not affect the safety and effectiveness of the proposed device.

SE Analysis 17- Average emergency lamp life

The proposed Light Sources have longer average emergency lamp life than that of the predicate device. This difference on average emergency lamp life does not affect the safety and effectiveness of the proposed device.

SE Analysis 18- Automatic exposure

Both the proposed device and predicate device provide the function of automatic exposure. Although the adjustable levels are different between the proposed device and predicate device, they all can achieve the purpose of image brightness adjustment. Therefore this item is considered as substantial equivalence.

Table 6 Safety Comparison

Proposed device: HD-500 Video Endoscope System

Predicate device: EVIS EXERA II 180 SYSTEM

| ITEM | Proposed Device<br>HD-500 Video Endoscope System | | Predicate Device<br>K100584<br>EVIS EXERA II 180 SYSTEM | |
|---|---|---|---|---|
| Electrical Safety | Comply with IEC 60601-1 | | Comply with IEC 60601-1 | |
| EMC | Comply with IEC 60601-1-2 | | Comply with IEC 60601-1-2 | |
| Particular requirements | Comply with IEC 60601-2-18 | | Comply with IEC 60601-2-18 | |
| Product Performance | Comply with ISO 8600-1 and ISO 8600-7 | | Comply with ISO 8600-1 and ISO 8600-7 | |
| Patient-contact component and material *(SE Analysis 19)* | Insertion section | PU, fluoroelastomer | Insertion section | Unknown |
| | Distal end | PEEK, Sapphire crystal SUS 304 | Distal end | Unknown |
| | Adhesive | Epoxy resin | Adhesive | Unknown |
| Biocompatibility *(SE Analysis 19)* | Cytotoxicity, ISO 10993-5 | | Unknown | |
| | Sensitization, ISO 10993-10 | | | |
| | Irritation, ISO 10993-10 | | | |

SE Analysis 19- Patient-contact component and material /Biocompatibility

The patient-contact components of the proposed device are same as those of the predicate device. Although the patient-contacting materials of the predicated device are unknown, the proposed device is biocompatible and conforms to ISO 10993 series standards. Therefore, the proposed device is claimed to be substantially equivalent to the predicate devices.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis in section 8 and the side-by-side optical performance tests, the proposed device and the predicate device have the same intended use, comparable product specification and optical performance. Therefore, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.