September 2, 2020

HuiZhou Xzing Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 200120
CHINA

Re: K192704
Trade/Device Name: Endofresh Digestive Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, FDS
Dated: September 23, 2019
Received: September 27, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, PhD
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192704

Device Name
Endofresh Digestive Endoscopy System

Indications for Use *(Describe)*

XZING-W200B Disposable GI Endoscope
The disposable GI endoscope (XZING-W200B) is designed to be used with XZING-S2 Camera System, monitor and other peripheral device for endoscopic observation, diagnosis and treatment of the adult upper gastrointestinal tract. It is a single use disposable device and cannot be reused.

XZING-C200B Disposable Colonoscope
The Disposable Colonoscope (XZING-C200B) is designed to be used with XZING-S2 Camera System, monitor and other peripheral device for electronic colonoscope observation, diagnosis and treatment of the adult lower digestive tract (including the anus, rectum, colon and ileocecal segment). It is a single use disposable device and cannot be reused.

XZING-S2 Camera System
The Camera System is designed to be used with the XZING endoscopes, monitor and other peripheral device for endoscopic observation, diagnosis and treatment.

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.

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510(k) Summary

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

The assigned 510(k) Number: K192704

1. Date of Preparation: 8/21/2020

2. Sponsor Identification

HuiZhou Xzing Technology Co., Ltd.

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Endofresh Digestive Endoscopy System
Common Name: Endoscopic Video Imaging System
Primary Components:

Endofresh Digestive Endoscopy System	Disposable GI endoscope	Model: XZING-W200B
	Disposable colonoscope	Model: XZING-C200B
	Camera System	Model: XZING-S2

Components 1
Trade Name: Disposable GI Endoscope:
Common Name: Endoscopic Video Imaging System
Model: XZING-W200B

Components 2
Trade Name: Disposable Colonoscope
Common Name: Endoscopic Video Imaging System
Model: XZING-C200B

Components 3
Trade Name: Camera System
Common Name: Endoscopic Video Imaging System
Model: XZING-S2

Regulatory Information

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

5. Identification of Predicate Device

510(k) Number: K100584
Product Name: EVIS EXERA II 180 System
Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

Components 1
Trade name: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE
Component Models: OLYMPUS GIF-Q180

Components 2
Trade name: EVIS EXERA II COLONOVIDEOSCOPE
Component Models: OLYMPUS CF-Q180AL

Components 1
Trade name: EVIS EXERA II VIDEO SYSTEM CENTER
Component Models: OLYMPUS CV-180

6. Indications for Use:

XZING-W200B Disposable GI Endoscope

The disposable GI endoscope (XZING-W200B) is designed to be used with XZING-S2 Camera System, monitor and other peripheral device for endoscopic observation, diagnosis and treatment of the adult upper gastrointestinal tract. It is a single use disposable device and cannot be reused.

XZING-C200B Disposable Colonoscope

The Disposable Colonoscope (XZING-C200B) is designed to be used with XZING-S2 Camera System, monitor and other periphearl device for electronic colonoscope observation, diagnosis and treatment of the adult lower digestive tract (including the anus, rectum, colon and ileocecal segment). It is a single use disposable device and cannot be reused.

XZING-S2 Camera System

The Camera System is designed to be used with the XZING endoscopes, monitor and other peripheral device for endoscopic observation, diagnosis and treatment.

Device Description

The proposed system, Endofresh Digestive Endoscopy System, includes a disposable GI endoscope, a disposable colonoscope and a camera system (refer to Table 1) They are used together with the monitor and other peripheral device for electronic endoscopic observation, diagnosis and treatment of adult upper gastrointestinal tract or adult lower digestive tract.

The disposable GI endoscope and disposable colonoscope are the hand-held, direct-viewing flexible endoscope used for endoscopy and endoscopic surgery within the upper and lower gastrointestinal tract. There are two LED lamps to provide illumination for endoscopic diagnosis, treatment and video observation. The disposable GI endoscope and disposable colonoscope are sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

The camera system is a video processing system which is designed to be used with the proposed endoscopes, monitor and other peripheral device. The camera system only has one imaging mode, white light imaging mode. Apart from the image processing functions, it also provides power supply for the endoscopes.

The display is not included in the Endofresh Digestive Endoscopy System. The display should have following color performance and color space to ensure the color performance of the whole system.

Table 1 Recommended Color performance and color space of display

Effective display area	576(H) × 324(V)mm
resolution	1920 (RGB) × 1080
Pixel pitch	0.300(H) × 0.300(V)mm
Displayed color	1.07billion (true 10 bit)
Luminance (type)	450cd/m^2
Contrast (Min)	800:1

7. Substantially Equivalent (SE) Comparison

Table 2. General Comparison

ITEM	Proposed Device	Predicate Device K100584	Remark
Product Code	FDF and FDS	NWB, FDF and FDS	Analysis 1
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	SE
Class	II	II	SE
Indications for Use	Disposable GI Endoscope The Disposable GI Endoscope (XZING-W200B) is designed to be used with XZING-S2 Camera System, monitor and other peripheral device for endoscopic observation, diagnosis and treatment of the adult upper gastrointestinal tract. It is a single use disposable device and cannot be reused.	EVIS EXERA II GASTROINTESTINAL VIDEOSOOPE OLYMPUS GIF TYPE Q180, OLYMPUS GIF TYPE H180 These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, Endo Therapy 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).	Analysis 2
	Disposable Colonoscope The Disposable Colonoscope is designed to be used with XZING-S2 Camera System, monitor and other periphearl device for electronic colonoscope observation, diagnosis and treatment of the adult lower digestive tract (including the anus, rectum, colon and ileocecal segment).	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL. OLYMPUS CF TYPE Q180AI. 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	

	It is a single use disposable device and cannot be reused.	equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).	
	XZING-S2 The Camera System is designed to be used with the XZING endoscopes, monitor and other peripheral device for endoscopic observation, diagnosis and treatment.	EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 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.	
Single use / Reuse	Endoscopes: Single use Image processor/camera system: Reuse	Endoscopes: Reuse Image processor/camera system: Reuse	Analysis 1
Sterile	Yes for disposable endoscope	No	
Target population	Adult	No special requirements	
Configuration (primary components)	/	Light Source	Analysis 3
	Image processor	Image processor	
	Video Disposable GI Endoscopy	Video Gastroscope	
	Video Disposable Colonoscope	Video Colonoscope	
	Accessories and peripheral devices	Accessories and peripheral devices	

Analysis 1- Product Code

This product has only white light mode, and the device of the comparative product has narrowband imaging (NBI), so the product code is FDF and FDS, excluding NWB. The code of proposed device is included in the code of the predicate device, the difference of the code will not affect the safety and effectiveness of the device.

Analysis 2- Indications for use, single use / reuse, sterile and target population

The Endofresh Digestive Endoscopy System and predicate device are difference on the indications for use, sterile and target population.

The endoscope of the predicate device is non-sterile and reusable. The endoscope must be cleaned and disinfected after and before every usage. The proposed endoscope is single use and provided sterile. It doesn't need reprocessing and reduces the risk of cross contamination.

The target population of the proposed device is adult, and the target population of the predicate device is

not specified. To specify the target population can help the clinician select the proper endoscope.
Based on above analysis, we think the differences on the indications for use, sterile and target population will not raise new questions on the safety and effectiveness of the proposed device.

Analysis 3-Configuration

The configuration of the proposed device is different from the predicate device. The proposed device has two LEDs on the distal end of the endoscope and the predicate device has an external LED source. The LEDs on the distal end of the endoscope have the same role as that of the external light source, and the internal LED light source of the proposed device makes operating the device less cumbersome. Therefore, this difference on light source does not affect the safety and effectiveness of the proposed device.

Table 3. Specifications Comparison of Disposable GI Endoscope

ITEM	Proposed device	Predicate device K100584	Remark
Model	XZING-W200B	GIF-Q180	/
Field of view	100°±10%	140°	Analysis 4
Depth of focus	3-100mm	3-100mm	SE
Front view	0°	0°	SE
Sensor type	CMOS	color CCD	Analysis 5
Distal end outer diameter	11mm	8.8mm	Analysis 6
Insert section outer diameter	11mm	8.8mm	Analysis 6
Bend angle	UP:180° DOWN:160° RIGHT:160° LEFT:160°"	UP:210° DOWN:90° RIGHT:100° LEFT:100°"	Analysis 7
Work length	1300mm	1030mm	Analysis 8
Biopsy channel inner diameter	3.2mm	2.8mm	Analysis 6

Analysis 4-Field of view

The field of view of Disposable GI Endoscope is different from that of the predicate device. The field of view of the proposed device 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.

Analysis 5-Sensor type

The sensor type of Disposable GI Endoscope is different from that of the predicate device. 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.

Analysis 6-Diameters

The Distal end outer diameter, Insert section outer diameter and Biopsy channel inner diameter of Disposable GI Endoscope is similar as those of the predicate devices. Those diameters meet the industrial standard. Therefore, this item is considered substantially equivalent.

Analysis 7-Bend Angle

The bend angles of Disposable GI Endoscope are similar as those of the predicate devices. The subject endoscopes are the electronic flexible endoscopes; it bends up, down, left, and right through the bending section (Bending angles of up to 160° in all directions can be assisted to it gives all-round observation angle >360°) by bending up/down/left/right of endoscope's bending section. The subject endoscopes meet the angle requirement during endoscopic observation and disgnosis of upper/lower gastrointestinal tract; We think this slight difference on bend angle between the proposed device and predicate devices does not affect the safety and effectiveness of the proposed device.

For the convenience of the surgeons, all of the optical properties of the proposed device have been included in the user manual, including bend angle. The surgeon will select the proper endoscope cope based on her/his experiences and clinical conditions.

Analysis 8- Working length

The working length of Disposable GI Endoscope is similar as that of the predicate devices. And the working length of proposed device meets the requirements of ISO 8600-1 standard. There are many legally marketed endoscope with different working lengths. Therefore, this difference on working length does not affect the safety and effectiveness of the proposed device.
For the convenience of the surgeons, all of the optical properties of the proposed device have been included in the user manual, including working length. The surgeon will select the proper endoscope cope based on her/his experiences and clinical conditions.

Table 4. Specifications Comparison of Disposable Colonoscope

ITEM	Proposed device	Predicate device K100584	Remark
Model	XZING-C200B	CF-Q180AL	/
Field of view	110°±10%	170°	Analysis 9
Depth of focus	3-100mm	3-100mm	SE
Front view	0°	0°	SE
Sensor type	CMOS	color CCD	Analysis 10
Distal end outer diameter	14mm	13.2mm	Analysis 11

Insert section outer diameter	14mm	12.8mm	Analysis 11
Bend angle	UP:180° DOWN:180° RIGHT:160° LEFT:160°	UP:180° DOWN:180° RIGHT:160° LEFT:160°	SE
Work length	1300mm	1680mm	Analysis 12
Biopsy channel inner diameter	3.2mm	3.7mm	Analysis 11

Analysis 9-Field of view

The field of view of Disposable Colonoscope is different from that of the predicate device. The field of view of the proposed device 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.

Analysis 10-Sensor type

The sensor type of Disposable Colonoscope is different from that of the predicate device. 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.

Analysis 11-Diameters

The Distal end outer diameter, Insert section outer diameter and Biopsy channel inner diameter of Disposable Colonoscope is similar as those of the predicate devices. Those diameters meet the industrial standard. Therefore, this item is considered substantially equivalent.

Analysis 12- Working length

The working length of Disposable Colonoscope is similar as that of the predicate devices. And the working length of proposed device meets the requirements of ISO 8600-1 standard. There are many legally marketed colonoscope with different working lengths. Therefore, this difference on working length does not affect the safety and effectiveness of the proposed device.
For the convenience of the surgeons, all of the optical properties of the proposed device have been included in the user manual, including working length. The surgeon will select the proper colonoscope cope based on her/his experiences and clinical conditions.

Table 5. Specifications Comparison of Camera System

ITEM	Proposed Device	Predicate Device K100584	Remark
Model	XZING-S2	OLYMPUS CV-180	SE
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz	SE
Over-current protection	Fuse type	Fuse type	SE
Input current	65VA	150VA	Analysis 13
Video signal output	DVI:2	RGB:3 Y/C:4 VBS:4 HDTV:1	Analysis 14
Auto white balance	Automatically adjusted	Automatically adjusted	SE
Automatic gain control	Provided	Provided	SE
Image modes	White-light imaging	White-light imaging Narrow Band Imaging (NBI) modes.	Analysis 15
Communication with endoscope	Provided	Provided	SE
Foot switch connector	Provided	Provided	SE
Pixel	2 million pixels	Unknown	Analysis 16
Resolution	1600*1200	4096*2160 3840*2160 1920*1080	Analysis 17

Analysis 13-Input Current

The input current of Camera System 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.

Analysis 14-Video Signal Output

The types of video signal output are different between camera system and predicate device. However, both the proposed system and predicate system are the high-definition endoscope system. High-definition interface: DVI interfaces are substantially equivalent to the HDTV interface. Therefore, the difference on video signal output will not affect the safety and effectiveness of the proposed device.

Analysis 15-Imaging mode

The proposed device only has white-light imaging mode. This white-light imaging mode of proposed

device is substantially equivalent to the white-light imaging mode of predicate device.

Analysis 16-Pixel

The pixel of predicate device is unknown, the proposed device pixel is 2 million pixels. High resolution means that the pixels of the sensor are greater than or equal to 1.3 million, and the pixels of the proposed device are already higher than 1.3 million, so the proposed device can clearly see the scene inside the patient. In addition, electrical safety and EMC test has been conducted on the proposed device and the test result can comply with related standards requirement. Therefore, this difference will not affect substantial equivalence between proposed device and equivalent device.

Analysis 17- Resolution

The proposed device resolution is 1600×1200pxl, the predicate device has 4069×2160 pxl, 3840×2160, 1920×1080 resolution can be select. The resolution for device is mainly related to the horizontal and vertical proportion of the display, and electrical safety and EMC test has been conducted on the proposed device and the test result can comply with related standards requirement. Therefore, this difference will not affect substantial equivalence between proposed device and equivalent device.

Table 6. Safety Comparison

ITEM	Proposed device	Predicate device K100584	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Particular requirements	Comply with IEC 60601-2-18	Comply with IEC 60601-2-18	SE
Product Performance	Comply with ISO 8600-1 and ISO 8600-7	Comply with ISO 8600-1 and ISO 8600-7	SE
Patient-contact component and material	Refer to ***Tab 12 Biocompatibility***	Unknown	Analysis 18
Biocompatibility	Cytotoxicity: ISO 10993-5	Unknown	Analysis 18
	Sensitization: ISO 10993-10		
	Irritation: ISO 10993-10		

Analysis 18- Patient-contact component and material / Biocompatibility

Although the patient-contacting materials of the predicated device are unknown, the Disposable GI Endoscope is biocompatible and conforms to ISO 10993 series standards. Therefore, the proposed device is claimed to be substantially equivalent to the predicate devices.

8. 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:

- ISO 10993-7:2008 Biological evaluation of medical devices— Part 7: Ethylene oxide sterilization residuals
- USP41-NF36 <85> Bacterial Endotoxins Test
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 8600-1:2015 Endoscopes — Medical endoscopes and endotherapy devices — part 1: General requirements
- ISO 8600-3:1997/Amd1:2003 Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes -- Medical endoscopes and endotherapy devices -- Part 4: Determination of maximum width of insertion portion
- 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
- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance, including the US National Differences
- IEC 60601-1-2:2014 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
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Device.
- IEC 62471:2006 Photobiological Safety of Lamps and Lamp Systems.
- ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.