DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 2, 2017

Karl Storz Endoscopy-America, Inc.
Nozomi Yagi, MAS, RAC
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K161554
Trade/Device Name: ENDOFLATOR 40 & 50
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV, FCX
Dated: January 26, 2017
Received: January 27, 2017

Dear Nozomi Yagi:

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. 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); 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

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)*
K161554

Device Name
ENDOFLATOR 40&50

Indications for Use *(Describe)*
The ENDOFLATOR 40 & 50 are used to create and/or to distend a cavity in the following diagnostic and therapeutic interventions:

- Laparoscopy
- Pediatric Laparoscopy
- Endoscopy of the Lower Gastrointestinal Tract (e.g., TEO, colonoscopy)
- Endoscopic Vessel Harvesting

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Nozomi Yagi Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	February 28, 2017
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: ENDOFLATOR 40 and ENDOFLATOR 50 Classification Name: Insufflator, Laparoscopic (21 CFR Part 884.1730)
Regulatory Class:	II
Product Code:	HIF (Insufflator, Laparoscopic), OSV(Insufflator, Endoscopic Vessel Harvesting), FCX(Insufflator, Automatic Carbon-Dioxide For Endoscope)
Guidance Document:	*Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)* issued on August 1, 1995 for Product Code HIF
Predicate Device(s):	Primary Predicate Device: World of Medicine's Insufflator 50L FM 134 (K153513) Second Predicate Device: Olympus Medical Systems Corp's High Flow Insufflation Unit UHI-4 (K122180)
Device Description:	This submission includes two microprocessor controlled CO_2 insufflators that have been developed in parallel: ENDOFLATOR 40 (Model Number: UI400) and ENDOFLATOR 50 (Model Number: UI500), both of which come with HIGH FLOW and PEDIATRICS modes. The HIGH FLOW mode has the pressure range of 1-30 mmHg and the flow rate range of 1-40 LPM (ENDOFLATOR 40) and 1-50 LPM (ENDOFLATOR 50). The PEDIATRICS mode has the pressure

<table>
<tr><td></td><td>range of 1-15 mmHg and the flow range of 0.1-15 LPM.

The ENDOFLATOR 40 &50 have redundant pressure and flow monitoring, automatic pressure relief, user control via graphical user interface and display of pressures/flow rates/ volume/operating mode.

The ENDOFLATOR 50 has three extra features not included in the ENDOFLATOR 40: (1) the higher maximum flow rate (50LPM), (2) the integrated gas heater, and (3) the ability for the user to save up to 30 procedure settings. Because the ENDOFLATOR 40 does not have the integrated gas heater, it can only be used with non-heated insufflation tubing set (Model Number: 031200-01). On the other hand, the ENDOFLATOR 50 (Model Number: UI500) can be used with either the non-heated insufflation tubing set (Model Number: 031200-01) or the heatable insufflation tubing set (Model Number: 031210-01).</td></tr>
<tr><td>Intended Use:</td><td>CO_2 insufflators and their accessories are used to create and/or to distend a cavity during diagnostic or therapeutic endoscopic interventions.</td></tr>
<tr><td>Indications For Use, Comparison</td><td>
<table>
<tr><th>Subject Device

ENDOFLATOR 40&50</th><th>Primary predicate device, K153513

W.O.M. Insufflator 50L FM134</th><th>Secondary predicate device, K122180

Olympus High Flow Insufflation Unit UHI-4</th></tr>
<tr><th colspan="3">Indication for Use</th></tr>
<tr><td>The ENDOFLATOR 40&50 are used to create and/or to distend a cavity in the following diagnostic and therapeutic interventions:
• Laparoscopy
• Pediatric Laparoscopy
• Endoscopy of the Lower Gastrointestinal Tract: (e.g., TEO, colonoscopy)
• Endoscopic Vessel Harvesting</td><td>The Standard, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.</td><td>This instrument is intended to insufflate the abdominal cavity and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis and treatment.
This instrument is intended for controlled CO_2 insufflation to create a cavity along the saphenous vein and/or radial artery to facilitate observation during an endoscopic vessel harvesting procedure.
This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.</td></tr>
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</td></tr>
</table>

	W.O.M. Insufflator 50L FM134 was chosen for having the Indication for Use and Technological Characteristics most similar to the subject device. The subject device differs from the primary predicate in that an operation mode is not specific to indicated intervention; the subject device has HIGH FLOW mode to cover laparoscopy, endoscopy of lower GI tract, and endoscopic vessel harvesting indications and PEDIATRICS mode to cover pediatric laparoscopy indication. Olympus' High Flow Insufflation Unit UHI-4 was chosen as a secondary predicate device to support the substantial equivalence of the additional anatomical location of use (i.e., colon) that the primary predicate does not include. The subject device has the same Intended Use as both primary and secondary predicate devices.
Technological Characteristics:	The subject and both primary and secondary predicate devices are CO_2 insufflators that are used to create and maintain the cavity. There are similarities and differences in the technological characteristics including but not limited to the following:

	Subject Device	**Primary predicate device, K153513**	**Secondary predicate device, K122180**
Distension Medium	CO_2	Same as the subject device	Same as the subject device
Indicated Population	Adult and Pediatric	Same as the subject device	Adult
Modes	High Flow, Pediatrics	Bariatric, Standard, Vessel Harvest, Pediatric	Normal Cavity, Small Cavity
Maximum Flow Rate	50 LPM	Same as the subject device	45 LPM
Maximum Pressure	30 mmHg	Same as the subject device	25 mmHg
Overpressure Action	Visual and audible alarms followed by pressure relief after 5 seconds	Visual and audible alarms followed by pressure relief after 2-5 seconds	Visual and audible alarms followed by pressure relief after 0 or 4.5 seconds
Gas Supply Shortage Action	When cylinder pressure is below 1 bar, visual and audible alarms will be activated and insufflation stops	At <15 bar, visual and audible alarms will be activated and insufflation stops	When cylinder pressure is below 0.1 MPa (1 bar), visual and audible alarms will be activated and insufflation stops
Over Temperature Action	At >41ºC, Information signal indicates that heating is switched off	At >42ºC, visual and audible alarm	N/A, gas is not heated

	The differences do not raise different questions of safety and effectiveness.
Non-Clinical Performance Data:	The ENDOFLATOR 40 & 50 is tested according to the following standards: • IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + AM1 (2012) • IEC 60601-1-2:2014 • IEC 60601-1-18:2006/AMD1:2012 Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff titled *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator. In addition, the following bench testing has been performed for following safety and performance requirements as well as for comparative purposes: **Bench Testing Summary**

Verification Test (Test#)	Acceptance Criteria	Conclusion
Safety – Overpressure	The device informs user, if an unintended high cavity pressure is measured and activates appropriate valves if the activation threshold is exceeded.	Pass
Performance -- Pressure	The difference between the measured and the set point pressures is within the specified limits.	Pass
Safety –Maximum pressure	The measured pressure shall not exceed the mode related specified limits.	Pass
Safety – Overpressure	The gas flow is stopped if a cavity pressure is measured is higher than mode related limits.	Pass
Performance – Gas supply	The device informs the user if the pressure gas supply falls under specified limits.	Pass
Performance -- Flow	The difference between the measured and the set point flow is within the specified limits.	Pass
Safety – Pressure Controller	The pressure controller temperature shall stain within the specified limits.	Pass
Safety – Overtemperature	(ENDOFLATOR 50 only) The heater is switched off if the fault arises.	Pass
Performance – Temperature	(ENDOFLATOR 50 only) The measured temperature is within the	Pass

		specified limits.	
	Performance – Heater connection symbol	(ENDOFLATOR 50 only) The heater connection symbol is correctly displayed.	Pass
	Comparative -- Adult and Pediatric Laparoscopy	To support laparoscopy indication of the subject device, the pressure control of High Flow mode must be substantially equivalent to the primary predicate device's Standard/Bariatric modes and the secondary predicate device's Normal Cavity mode. Similarly, to support Pediatric Laparoscopy indication of the subject device, the pressure control of Pediatrics mode must be substantially equivalent to the primary predicate device's Pediatric mode.	SE to predicate devices
	Comparative – Lower Gastrointestinal Tract	In order to support lower gastrointestinal indication of the subject device, the pressure control of High Flow mode must be substantially equivalent to the secondary predicate device's Small Cavity mode.	SE to predicate devices
	Comparative – Endoscopic Vessel Harvesting	In order to support Endoscopic Vessel Harvesting indication of the subject device, the pressure control of High Flow mode must be substantially equivalent to the primary predicate device's Vessel Harvesting mode and the secondary predicate device's Small Cavity mode.	SE to predicate devices
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.		
Conclusion:	The conclusions drawn from the nonclinical tests such as the software data, the electrical safety and performance data, as well as the bench top performance data, demonstrated the subject device is as safe as and as effective as the primary and secondary predicate devices. As such, we concluded that the substantial equivalence of the subject and both predicate devices has been met.		