June 22, 2020

OMEC Medical, Inc.
% Ms. Yolanda Smith
Sr. Regulatory Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114
Re: K201151
Trade/Device Name: O-Mec Laparoscopes 690 Series (Models 690- 331000H, 690-331030H, 690-300500H, 690-300530H)

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 14, 2020
Received: April 29, 2020

Dear Ms. Smith:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K201151

Device Name
O-Mec Laparoscopes 690 Series (Models, 690-331000H, 690-331030H, 690-300500H, 690-300530H)

Indications for Use *(Describe)*
The O-Mec Laparoscopes 690 Series (Models, 90-331000H, 690-331030H, 690-300500H, 690-300530H) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments.

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

1. Submitter Information

Company Name:	OMEC Medical Inc.
Company Address	2370 Qume Drive, Suite A San Jose, CA 95131
Telephone:	408-667-5307
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Contact Person:	Ms. Claire Nippress
Email:	clairen@omectech.us

2. Correspondent Information

Contact:	Ms. Yolanda Smith Sr. Regulatory Consultant Smith Associates
Address:	1468 Harwell Ave Crofton, MD 21114
Phone:	(410)451-0639 Ysmith9746@fdaconsultants.com

3. Date Prepared: June 17, 2020

4. Device Name

Classification Name:	Laparoscope, General & Plastic Surgery
Common/Usual Name:	Laparoscope
Proprietary Name:	O-Mec Laparoscopes 690 Series (Models 690- 331000H, 690-331030H, 690- 300500H, 690-300530H)
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Device Class:	Laparoscopes 21 CFR 876.1500
Reviewing Panel:	General & Plastic Surgery
Basis for Submission:	New device 510k

5. Predicate Device

Legally Marketed Equivalent Device

	Manufacturer	Brand Name	510(k) Number
Primary	Stryker Endoscopy	Stryker Bariatric Laparoscope	K993045
Reference	Schoelly Fiberoptics GmbH	Schoelly Laparoscope	K143221
Reference	Stryker Corporation	Stryker Laparoscope	K910132

6. Device Description

O-Mec laparoscopes 690 Series Models 690- 331000H, 690-331030H, 690-300500H, 690-300530H are rigid endoscopes that are used to view a patient's internal anatomy for examination, diagnosis and therapy during laparoscopic procedures. An endoscope is a slender, tubular optical instrument used as a viewing system for examining an inner part of the body. The inside of the endoscope contains a series of lenses that transmit the endoscopic image, which is illuminated by an external light source.

O-Mec laparoscopes 690 Series Models 690- 331000H, 690-331030H, 690-300500H, 690-300530H are available in two sizes: 5mm or 10mm diameters, with either 0^o or 30^o directions of view. O-Mec laparoscope provides a high definition image and can correct chromatic aberration in the 400-900nm wavelength range.

O-Mec laparoscopes 690 Series Models 690- 331000H, 690-331030H, 690-300500H, 690-300530H are delivered non-sterile and are reusable and fully autoclavable. O-Mec laparoscopes must be cleaned according to the Instructions of Use before each use.

Table 1: Model Specifications - 690 Series

Catalog No.	Working Length	Maximum Width of Inserted Portion	Direction of View
690-331000H	331mm	10.1mm	0^o
690-331030H	334mm	10.1mm	30^o
690-300500H	301mm	5.5mm	0^o
690-300530H	303mm	5.5mm	30^o

7.Indications for Use

The O-Mec Laparoscopes 690 Series (Models, 90-331000H, 690-331030H, 690-300500H, 690-300530H) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

8. Comparison of Technical Characteristics

The table below lists the comparison of the indications for use and technological characteristics of the subject and predicate device.

Table 2: Comparator table for Subject Device

Parameter	Subject Device	Primary Predicate Device	Reference K143221	Comments
510(k) Number	K201151	K993045	K143221	
Brand Name	690 Series	Stryker Bariatric Laparoscope	Schoelly Laparoscope	

Parameter	Subject Device K201151	Predicate Device K993045	Predicate Device K143221	Comments
Regulation Number	876.1500	876.1500	876.1500	Same
Regulation Name	Laparoscope, general & Plastic Surgery	Endoscope and Accessories	Endoscope and Accessories	Same
Product Code	GCJ	GCJ	GCJ	Same
Indications for Use	The O-Mec 690 Series Laparoscopes (690-331000H, 690-331030H, 690-300500H, 690-300530H) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments.	Laparoscopes are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments. This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, gastric bypass, laparoscopic Nissen and examination of the abdominal cavity, appendix, gallbladder and liver.	The Schoelly Laparoscope is indicated for examination of body cavities, hollow organs, and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures.	Similar
Principle of Operation	Rigid, tubular, optical instrument through an incision in the abdominal wall, used to examine organs inside the abdomen.	Rigid, tubular, optical instrument through an incision in the abdominal wall, used to examine organs inside the abdomen.	Rigid, tubular, optical instrument through an incision in the abdominal wall, used to examine body cavities, hollow organs, and canals.	Similar
Models Feature Comparison				

Parameter	Subject Device K201151	Predicate Device K993045	Predicate Device K143221	Comments
Catalog no	690-331000H	502-537-010	11.0031a	
Working Length	331mm	300mm	344mm	Similar
Maximum Width of inserted Portion	10.1mm	Ø10.0mm	10.0mm	Similar
Direction of view	0^0	0^0	0^0	Same
Catalog no	690-331030H	502-537-030	11.0043a	
Working Length	334mm	300mm	344mm	Similar
Maximum Width of inserted Portion	10.1mm	Ø10.0mm	10.0mm	Similar
Direction of view	30^0	30^0	30^0	Same
Catalog no	690-300500H	502-937-010	N/A	
Working Length	301mm	300mm	312mm	Similar
Maximum Width of inserted Portion	5.5mm	Ø5.5mm	5.0mm	Similar
Direction of view	0^0	0^0	0^0	Same
Catalog no	690-300530H	502-937-030	N/A	
Working Length	303mm	300mm	312mm	Similar
Maximum Width of inserted Portion	5.5mm	Ø5.5mm	5.0mm	Similar
Direction of view	30^0	30^0	30^0	Same
Optical System				

Parameter	Subject Device K201151	Predicate Device K993045	Predicate Device K143221	Comments
Depth of Field	25mm to 150mm	N/A	N/A	Information not available
Field of View	75°	N/A	Wide angle	Only wide angle referenced
Correct Chromatic Aberration	400-900nm wavelength range	N/A	N/A	Reference predicate K910132
Material Choices				
Body Assembly	Stainless Steel 304 Stainless Steel 316L Optical Glass Sapphire Epoxy Glue	Stainless Steel Optical glass	Stainless Steel 304 Optical Glass	Similar
Eyepiece Eyepiece is standard: ISO/TS 18339:2015-11 Endotherapy devices - Eyepiece cap and light guide connector	Polyetheretherketone (PEEK)	Yes	Yes	Same
Accessories				
Cable Adapter Compatibility	Wolf Adapter Storz Adapter ACMI Adapter	N/A	N/A	
Non- sterile Delivered in non-sterile condition. Needs to be sterilized before each use.	Yes	Yes	Yes	Same
Autoclavable	Yes	Yes	Yes	Same
Reusable/ Reprocessable	Yes	Yes	Yes	Same

Reference Predicate
K910132 is included as a reference predicate for the 400-900nm wavelength. The subject and reference device have very minor modifications to enhance near infrared images.

9. Summary of Non-Clinical Testing

The following performance data were provided in support of the substantial equivalence determination.
Table 3: Summary Table of Non-Clinical Testing

Category	Test Title	Evaluation	Test Criteria	Results
Functional Performance	Laparoscope Performance Test	Marking		Met acceptance criteria
		Surface & Edges		Met acceptance criteria
		Connection		Met acceptance criteria
		Dimensions		Met acceptance criteria
		Cleanliness		Met acceptance criteria
		Aperture and Center Focus		Met acceptance criteria
		Evenness of Illumination		Met acceptance criteria
		Image Consistency and Depth of Field		Met acceptance criteria
		Image Focus and Color		Met acceptance criteria
		Reflection and Runout		Met acceptance criteria
		FOV/DOV		Met acceptance criteria
		MTF		Met acceptance criteria
		Transmission / Vignetting		Met acceptance criteria
		Distortion		Met acceptance criteria
		Runout		Met acceptance criteria
Sterilization / Cleaning Validation Studies	Manual/Mechanical Cleaning Validation GLP Report	Cleaning validation was performed for recommended procedures and Enzol detergent Hemoglobin Test Micro BCA Protein Test MEM Elution Test	AAMITIR30:2011	The cleaning study was successful in showing the reduction of the physical markers. This provides evidence that laparoscopes can be cleaned effectively using the instructions provided.
	Simulated Use Cycles Final Report	Six simulated use cycles were performed. Each cycle included soiling, cleaning and	AAMITIR30:2011	No soil was observed on any of the articles.

Category	Test Title	Evaluation	Test Criteria	Results
		sterilization procedures Article oiling ManualCleaning procedure Sterilization		
	Steam Sterilization validation Final Report	Test article was evaluated to a sterility assurance level (SAL) of $\leq 10^{-6}$	ANSI/AAMI/ISO 17665-1:2006/®2013, Annex D and the validation approach outlined in ANSI/AAMI/ISO 14937:2009®2013, Annex D (Approach 3)	Results validated following sterilization set points: Sterilizer Type: Prevacuum Preconditioning Pulses: 4 Temperature: 132°C Full Cycle Time: 4 minutes Dry Time: 40 minutes Test Article Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Halyard Health H200 - 510(k) K082554) using sequential envelope folding techniques Load Configuration: One 20 pound tray filled with miscellaneous stainless steel dunnage was placed above the test article in the sterilizer
Electrical Safety	Medical electrical equipment Part 1 general requirements for basic safety and essential performance	Clause 5.7 Humidity Preconditioning Treatment Clause 5.9.2 Determination of Accessible parts Clause 7.1.2 Legibility of Marking Clause 7.1.3 Marking Durability Clause 8.7 Leakage current Clause 8.8.3 Dielectric strength test	IEC 60601-1 2005+A1:2012	Pass
	Medical electrical equipment Part 2: particular requirement for the basic safety and essential performance of endoscopic equipment		IEC60601-2-18	Pass

Category	Test Title	Evaluation	Test Criteria	Results
		Clause 11.1,. 1 w=Excessive temperatures Clause 15.3.2 Push test Clause 15.3.4.1 Drop test Clause 15.3.6 Mould stress relief test		
Hazard Analysis	Medical devices - Application of risk management to medical devices		ISO 14971 2nd Edition R 2010	

Clinical testing was not performed with this device.

10. Conclusion

The subject device is similar and or same for technological features to the predicate devices with slight differences for working length and width of inserted portion. The differences introduce not new issues of safety.