K123359

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510(k) Summary

DEC 19 2012

510(k) Submitter	Olive Medical Corp. 2302 South Presidents Dr. STE D Salt lake City, UT 84120
Contact(s) Telephone Fax	Brian Dean (801) 953-0559 (801) 823-2238
Date Prepared	October 26th, 2012
Trade Name	OVS1 Video System
Common Name	Endoscope And/Or Accessories
Classification Name Regulation Number Product Code	Light Source, Fiberoptic, Routine; Laparoscope, General & Plastic Surgery 21 CFR 876.1500 FCW; GCJ

Predicate Devices

Tele Pack X	Not known	Karl Storz Endoscopy- America, Inc
Image 1 Video Imaging System With Option	K070716	Karl Storz Endoscopy- America, Inc
InnerVue Diagnostic Scope System	K072879	Biomet Sports Medicine
Flexible Video Endoscope with Sheath and Video Processor	K102733	Vision-Sciences, Inc
LED Light Source	K093792	Sunoptic Technologies, Inc.

Device Description:

The OVS1 Video System is a Camera Control Unit with integrated LED Light Source and Video Display for use in a surgical environment to view endoscopic images when interfaced with the Olive Medical TCK1 HD Camera Head, an endoscope, a light cable, and other accessory devices.

Intended Use:

Indications for Use:

The OVS1 Video System is indicated for use in diagnostic and operative endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. The OVS1 Video System is indicated for use with a compatible Olive Medical Camera Head and other accessory devices including an endoscope, optical coupler, and light cable

This Indications for Use statement is substantially equivalent to predicate devices.

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General description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate:
The OVS1 Video System is intended for use in endoscopic procedures without limit to the diseases or condition being treated by the treating surgeon.

Patient Population for which the device is intended:
The OVS1 Video System is intended for use with patients undergoing endoscopic procedures for which the treating surgeon desires external video display and/or illumination.

Comparison of Technological Characteristics
The OVS1 Video System is substantially equivalent to predicate devices since the device technology and design are similar. The Indications for Use statements are similar to predicate devices, and no new issues of safety or effectiveness are raised. The minor differences between the OVS1 Video System and predicate devices have no negative effect on performance, function, or intended use of the device.

Device Comparison Tables:

	Display Technology	Display Size	Video Output Resolution (vertical lines)	Control Unit Technology
OVS1 Video System	Integrated LCD	12.1"	720	Similar
Tele Pack X Karl Storz Endoscopy- America, Inc 510(k) unknown	Integrated LCD	15"	494*	Similar
Image 1 Video Imaging System With Option Karl Storz Endoscopy- America, Inc K070716	N/A	N/A	N/A	Similar – no on-board display or Light Source
InnerVue Diagnostic Scope System Biomet Sports Medicine K072879	Integrated LCD	6.4"	480	Similar
Flexible Video Endoscope with Sheath and Video Processor Vision-Sciences, Inc K102733	Integrated LCD	15"	480	Similar
LED Light Source Sunoptic Technologies, Inc. K093792	N/A	N/A	N/A	N/A
Lightsource or Illuminator Sunoptic Technologies, Inc. K961074	N/A	N/A	N/A	N/A

*Output resolution unknown. Vertical lines of input listed

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	Light Source Technology	Light Source Safety
OVS1 Video System	LED	LED Module and output identical to LED Light Source, K093792
Tele Pack X Karl Storz Endoscopy- America, Inc 510(k) unknown	Metal Halide	Light Source Safety demonstrated in 510(k) submission
Image 1 Video Imaging System With Option Karl Storz Endoscopy- America, Inc K070716	N/A	N/A
InnerVue Diagnostic Scope System Biomet Sports Medicine K072879	Xenon Arc	Light Source Safety demonstrated in 510(k) submission
Flexible Video Endoscope with Sheath and Video Processor Vision-Sciences, Inc K102733	LED	Light Source Safety demonstrated in 510(k) submission
LED Light Source Sunoptic Technologies, Inc. K093792	LED	Light Source Safety demonstrated in 510(k) submission
Lightsource or Illuminator Sunoptic Technologies, Inc. K961074	Xenon	Light Source Safety demonstrated in 510(k) submission

	Performance Comparison	Target Population and Anatomical Site	Reuse durability	Skill Level Required
OVS1 Video System	Similar	Similar	Similar	Similar
Tele Pack X Karl Storz Endoscopy- America, Inc 510(k) unknown	Equivalent	Similar	Similar	Similar
Image 1 Video Imaging System With Option Karl Storz Endoscopy- America, Inc K070716	Similar, no on-board display or light source	Similar	Similar	Similar
InnerVue Diagnostic Scope System Biomet Sports Medicine K072879	Similar	Similar	Similar	Similar
Flexible Video Endoscope with Sheath and Video Processor Vision-Sciences, Inc K102733	Similar	Similar	Similar	Similar
LED Light Source Sunoptic Technologies, Inc. K093792	Identical light output	Similar	Similar	Similar
Lightsource or Illuminator Sunoptic Technologies, Inc. K961074	Similar	Similar	Similar	Similar

	Energy Source	Materials	Biocompatibility	Sterility
OVS1 Video System	External – wall outlet	Similar	N/A	N/A
Tele Pack X Karl Storz Endoscopy- America, Inc 510(k) unknown	External – wall outlet	Similar	N/A	N/A
Image 1 Video Imaging System With Option Karl Storz Endoscopy- America, Inc K070716	External – wall outlet	Similar - no on-board display or light source	N/A	N/A
InnerVue Diagnostic Scope System Biomet Sports Medicine K072879	External – wall outlet	Similar	N/A	N/A
Flexible Video Endoscope with Sheath and Video Processor Vision-Sciences, Inc K102733	External – wall outlet	Similar	N/A	N/A
LED Light Source Sunoptic Technologies, Inc. K093792	External – wall outlet	Similar – no on-board display	N/A	N/A
Lightsource or Illuminator Sunoptic Technologies, Inc. K961074	External – wall outlet	Similar – no on-board display	N/A	N/A

Non-Clinical Testing:
The OVS1 Video System demonstrates substantial equivalence in safety by tested compliance with ISO 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; and ISO 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests.

Clinical Testing:
No comparison of clinical performance data was used for demonstration of substantial equivalence

Substantial Equivalence Rationale:
The OVS1 Video System fulfills criteria regarding substantial equivalence with the Predicate Devices listed for the following reasons:

1. The intended use of the OVS1 Video System is equivalent to the Tele Pack X, 510(k) unknown; Image 1 Video Imaging System, K070716; and InnerVue Diagnostic Scope System, K072879
2. The Indications for Use statements are equivalent to the indications for use of the InnerVue Diagnostic Scope System, K072879, and the Flexible Endoscope Sheath and Video Processor, K102733
3. The Technologic characteristics of the OVS1 Video System are equivalent to Predicate Devices as follows:

a. Video Processing System Equivalence: Tele Pack X, 510(k) unknown; Image 1 Video Imaging System, K070716; InnerVue Diagnostic Scope System, K072879; and Flexible Endoscope Sheath and Video Processor, K102733
b. Light Source Similarity: Tele Pack X, 510(k) unknown; Flexible Video Endoscope with Sheath and Video Processor, K102733, Lightsource or Illuminator, K961074
c. Light Source Identical: LED Light Source, K093792
d. Display Equivalence: Tele Pack X, 510(k) unknown; InnerVue Diagnostic Scope System, K072879; and Flexible Endoscope Sheath and Video Processor, K102733

4. Performance data show no new safety concerns for the OVS1 Video System
5. Performance of the OVS1 Video System demonstrates equivalent ability to Predicate Devices to illuminate the surgical site, process video, and display video

510(k) Summary Final Criteria Checklist

- The summary includes only information that is also covered in the body of the 510(k).
- The summary does not contain any puffery or unsubstantiated labeling claims.
- The summary does not contain any raw data, i.e., contains only summary data.
- The summary does not contain any trade secret or confidential commercial information.
- The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2012

Olive Medical Corp.
% Mr. Brian Dean
VP, RA/QA
2302 South Presidents Dr. STE D
SALT LAKE CITY UT 84120

Re: K123359
Trade/Device Name: OVS1 Video System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCW, GCJ
Dated: October 29, 2012
Received: October 31, 2012

Dear Mr. Dean:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert R. Lerner

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

Indications for Use

510(k) Number (if known): K123359

Device Name:

OVS1 Video System

Indications For Use:

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Prescription Use ___XX____ And/Or Over-The Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123359