



Food and Drug Administration  
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October 13, 2015

W.O.M. World Of Medicine GmbH  
% Susanne Raab  
Regulatory Consultant  
Susan Raab  
1480 Cambridge Street  
Cambridge, MA 02139

Re: K152109  
Trade/Device Name: HD-Camera HDC1000  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FET, NTN  
Dated: July 24, 2015  
Received: July 29, 2015

Dear Susanne Raab,

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,

  
**Herbert P. Lerner -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

## Indications for Use

510(k) Number (if known)  
K152109

Device Name  
HD-CameraHDC1000

### Indications for Use (Describe)

The HD-Camera HDC1000 is intended to be used during diagnostic and operative endoscopic procedures to provide illumination and visualization of body cavities, hollow organs and canals and to allow for image recording and documentation. The HD-Camera HDC1000 is indicated for use with compatible rigid or flexible endoscopes and other video equipment and endoscopic accessories.

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.\***

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## **510(k) SUMMARY OF SAFETY & EFFECTIVENESS**

### **1) General Information:**

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**Date Prepared:** July 24, 2015

### **2) Proposed Device:**

**Trade Name:** HD-Camera HDC1000  
**Common Name:** Endoscopic Video Imaging  
System/Component, Gastroenterology-  
Urology  
**Classification Name:** Endoscope and accessories  
**Regulation Number:** 21 C.F.R. 876.1500  
**Regulatory Class:** II  
**Product Code:** FET, NTN

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**3) Predicate Devices:**

<b>Trade Name:</b>	OVS1 Video System
<b>510(k) Number:</b>	K024291
<b>Classification Name:</b>	Laparoscope, General and Plastic Surgery
<b>Regulation Number:</b>	21 C.F.R. 888.1100
<b>Regulatory Class:</b>	II
<b>Product Code:</b>	G CJ, FCW

**4) Device Description:**

The HD-Camera HDC1000 is a video-management system that consists of a camera, an integrated light source and a capture module for storing and compressing video and still images. It is used in conjunction with an endoscope or microscope, a light cable and other endoscopic accessories to illuminate surgical sites and to view the surgical sites on video monitors during diagnostic and operative endoscopic procedures. The camera of the proposed device consists of a camera control unit (CCU), a coupler, and a camera head with an integral cable that connects to the camera control unit (CCU). The optical image is transferred from the surgical site to the camera head by compatible rigid and flexible endoscopes that are attached to the camera head using an optical coupler. The camera head including camera cable and the coupler are reusable devices and must be sterilized using the STERRAD® advanced sterilization process or may be used with a sterile cover or sleeve. The camera control unit (CCU) is not intended to enter the sterile field, and cannot be sterilized.

**5) Intended Use:**

The HD-Camera HDC1000 is intended to be used during diagnostic and operative endoscopic procedures to provide illumination and visualization of



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body cavities, hollow organs and canals and to allow for image recording and documentation. The HD-Camera HDC1000 is indicated for use with compatible rigid and flexible endoscopes and other video equipment and endoscopic accessories.

**6) Comparison of Technological Characteristics:**

The proposed device HD-Camera HDC1000 and the predicate device OVS1 Video System incorporate the same basic design. Specifically, both the HD-Camera HDC1000 and the predicate device are 1-Chip cameras that consist of three main components: a camera head, various optical couplers, and a camera control unit (CCU). In addition, the HD-Camera HDC 1000 and the predicate device are designed with an integrated LED light source.

Both the HD-Camera HDC1000 and the predicate device receive optical images from a variety of scopes that are attached to the camera head via a coupler or direct attachment and use a CCD image sensor to convert the optical image into an electronic signal. The camera head of the HD-Camera HDC1000 and the predicate device incorporate a button keypad to control the system itself and any other connected video equipment.

The camera control unit (CCU) of the proposed device and the predicate device are software controlled and are equipped with a graphical user interface (GUI). The GUI of both the HD-Camera HDC1000 and the predicate device is designed with a menu key that allows the user to select and change various pre-programmed settings and to make changes in the assignment of the buttons on the keypad of the camera head.

The differences in the technological characteristics of both the proposed device HDC1000 and Predicate Device are minor and do not raise new questions of



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safety and effectiveness. The differences between the HDC1000 and the Predicate Device are the following:

- Unlike the camera head unit of the Predicate Device, the camera head unit of the proposed device can be sterilized.
- The button keypad of the camera head of the Predicate Device is designed with three buttons. The proposed device HDC1000 is designed with two camera head buttons.
- The camera head of the Predicate device incorporates a digital zoom feature whereas the proposed device HDC1000 is to be used with a zoom lens.
- The chip pixels of the camera head of the devices differ slightly. The camera head of the proposed device incorporates a chip with 1280 x 720 pixels versus 1920 x 1080 pixels of the predicate device.
- The proposed device HDC1000 has a frame rate of 30fps and the Predicate Device of 60fps.
- The CCU of the Predicate Device contains a touchscreen with a graphical interface including display. The HDC1000 is designed with a plastic foil keypad with a graphical interface and adjustments are only displayed on the monitor.
- The CCU of the Predicate Device offers fiberscope and ENT in addition to the above mentioned pre-programmed procedure profiles.
- The CCU of the proposed device incorporates two HDMI signal outputs and the Predicate device one DVI (HDMI), one 3G-SDI, one USB 2.0 and one Ethernet signal output.
- The resolution of the video output of the CCU of the HDC1000 is 1280 x 720 pixels versus 1920 x 1080 pixels of the Predicate device.



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- The CCU of the HDC1000 is designed to be used with a SDHC card as a storage media and that of the Predicate Device with a USB flash thumb.

**7) Performance Data:**

Electrical safety and electromagnetic compatibility testing was performed by independent laboratories in accordance with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;
- IEC60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests;
- IEC60601-2-18:2009 - Medical Electrical Equipment - Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment.

Test results demonstrate that the proposed device conforms to the above standards.

The software was developed, tested, and verified in accordance with the FDA guidance document, “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*” and in accordance with the following standard:

- IEC62304:2006 - Medical Device Software – Software Life Cycle Processes.



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The cleaning instructions provided in the labeling for the camera head and cable were validated. Sterilization validation testing was performed in accordance with the below standard:

- AAMI/ANSI/ISO 14937:2009 - Sterilization of Health Care Products — General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices;
- AAMI TIR12:2010 - Designing, Testing and Labeling reusable medical devices for reprocessing in health care facilities: A Guide for Medical Device Manufacturers.

Design verification testing of the HD-Camera HDC1000 demonstrates that the device performs as intended and that the performance does not raise new questions of safety and effectiveness.

Finally, comparative bench testing was performed to demonstrate that the performance of the HD-Camera HDC1000 is substantially equivalent to that of the predicate device OVS1 Video System. The comparative bench test included signal to noise ratio (SNR), resolution, latency, shading correction accuracy, white balance accuracy and maximum light source intensity.

**8) Conclusions:**

Based on the same intended use, the same basic technological characteristics and performance testing, the HD-Camera HDC1000 is substantially equivalent to the predicate device OVS1 Video System. The differences between the



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proposed device and the predicate device do not raise new questions of safety and effectiveness.