



Food and Drug Administration
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February 25, 2016

Orpheus Medical Ltd.
% Mr. Ian Marsden
Assistant Director Regulatory Affairs
Dohmen Life Sciences Services, LLC
11925 W I-70 Frontage Road North, Suite 900
Wheat Ridge, Colorado 80033

Re: K151737

Trade/Device Name: MedicVOD System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 1, 2016
Received: February 2, 2016

Dear Mr. Marsden:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151737

Device Name

MedicVOD System

Indications for Use (Describe)

The MedicVOD System is a picture archival and communications systems (PACS) that is intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The system allows for capture and annotation of the surgical procedure for documentation purposes and for viewing at a later time either locally or on a secure distributed network. The captured audio/video sequences can be broadcasted in real-time with video-conferencing capability during the broadcast. Information captured and stored by the system are for viewing and reference purposes only and are not intended for primary diagnosis.

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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Section 07: 510(k) Summary

1. Introduction

- 1.1 This document contains the 510(k) summary for the modified Orpheus Medical Ltd. MedicVOD System (K151737). The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

2. Applicant Name and Address

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Official Contact:	Ian Marsden Assistant Director of Regulatory Affairs Dohmen Life Science Services, LLC
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3. Summary Preparation Date: February 24, 2016

4. Device Name and Classification

Trade Name	MedicVOD System
Common Name	Picture Archiving and Communication System
Classification Name	Picture Archiving and Communication System
Classification	21 CFR 892.2050
Regulation	
Product Code	LLZ

5. Predicate Devices

- 5.1 The modified Orpheus Medical Ltd. MedicVOD System is claimed to be substantially equivalent to the following legally marketed predicate device:

5.1.1 Orpheus Medical Ltd. MedicVOD System (K123426)

6. Performance Standards

- 6.1 There are no mandatory performance standards for this device.

7. Device Description

- 7.1 Orpheus Medical MedicVOD System is a picture archiving and communication system intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The MediVOD System contains the following modules/components:

7.1.1 mediCast (ie mediCast Live) – a video stream / image capture device which is connected to a medical scope camera.

- 7.1.2 mediCast App – real-time compression and archiving application displaying session from mediCast Box or from any USB attached camera and broadcast it in real time.
 - 7.1.3 mediCast Mobile App - a smart phone application for uploading medical images and videos.
 - 7.1.4 mediCast Box – a video stream / image capture device which receives a video signal from various video sources. Connected to a computer via a USB adaptor and uses the mediCast App to display video.
 - 7.1.5 mediShow – a viewer for real-time broadcasting from a mediCast System.
 - 7.1.6 mediSearch – a search utility application which allows the user to search for and view videos and still images previously captured by mediCast.
 - 7.1.7 mediWeb – a web based application that provides access to the mediSearch and mediShow applications.
- 7.2 The MedicVOD System key features include:
- 7.2.1 Digital recording of medical procedures streamed directly to on-site server for storage and retrieval,
 - 7.2.2 Live broadcast of a medical procedure to an unlimited number of viewers,
 - 7.2.3 Archiving of video assets to a controlled storage resource,
 - 7.2.4 Data fetching with dynamic categories for statistical analysis and multiple report production, and
 - 7.2.5 Ability to view/review videos
- 7.3 The mediCAST box is capable of capturing and broadcasting a video stream in real time. MediCAST box captures and stores video and still images, and in parallel, uploads the captured images and video streams to the MedicVOD server. The mediCAST box uploads the videos and images when there is communication with the MedicVOD server.
- 7.4 The mediSearch application provides the ability to search within the MedicVOD archive. The mediSearch application allows users to perform searches for video recordings within a captured mediCAST session. Each session could be a combination of several recordings of various kinds. For example, a session could be a combination of several video recordings, several still images (snapshot taken) and several DICOM images that have been stored. MediSearch provides the ability to view the assets which were found, and provides certain editing capabilities.
- 7.5 The mediShow application automatically connects into the MedicVOD server and displays currently active sessions or procedures captured by any mediCAST station on the local network.

8. Comparison of Indications for Use to the Predicate Device

- 8.1 The modified MedicVOD System which is the subject of this submission has identical indications for use as identified in the original MedicVOD System cleared under K123426. The indications for use for the MedicVOD System are as follows:
- 8.1.1 The MedicVOD System is a picture archival and communications systems (PACS) that is intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The system allows for capture and annotation of the surgical procedure for documentation purposes and for viewing at a later time either locally or on a secure distributed network. The captured audio/video sequences can be broadcasted in real-time with video-conferencing capability during the

broadcast. Information captured and stored by the system are for viewing and reference purposes only and are not intended for primary diagnosis.

9. Comparison of Technological Characteristics to the Predicate Device

9.1 The modified MedicVOD System is substantially equivalent to the original MedicVOD System cleared under K123426 with the addition to the following modules/components to the System:

9.1.1 mediCast App – real-time compression and archiving application displaying session from mediCast Box or from any USB attached camera and broadcast it in real time.

9.1.2 mediCast Mobile App - a smart phone application for uploading medical images and videos.

9.1.3 mediCast Box – a video stream / image capture device which receives a video signal from various video sources. Connected to a computer via a USB adaptor and uses the mediCast App to display video.

9.2 The table below provides a comparison of the modified MedicVOD System which is the subject of this 510(k), to the original MedicVOD System cleared under K123426.

Specification	Modified Device	Unmodified MedicVOD System K123426	Comparison to Predicate
Device Name	MedicVOD System	MedicVOD System	Identical
System Configuration	Video, still Image and audio capturing workstation, central archiving server and view terminal/s	Video, still Image and audio capturing workstation, central archiving server and view terminal/s	Identical
Clinical Application	During and after surgical procedures	During and after surgical procedures	Identical
Hardware Configuration	Touch panel PC, external keyboard & mouse, footswitch, mediCast Box, Apple and Android based tablets and phones	Touch panel PC, external keyboard & mouse, footswitch	Substantially Equivalent
Data Storage	Internal storage and transmission to external central storage server	Internal storage and transmission to external central storage server	Identical
Operating System	Windows, iOS, Android based	Windows based	Substantially Equivalent
Image Sources	Laparoscopic images as well other audio/image/video outputs modalities	Laparoscopic images as well other audio/image/video outputs modalities	Identical
Signal Encryption	Encrypted digital transmission on session and tier base + Various authentication levels and external LDAP integration	Encrypted digital transmission on session and tier base + Various authentication levels and external LDAP integration	Identical
Resolution	Supports up to high definition :1920x1080	Supports up to high definition :1920x1080	Identical
Audio Compression	Mpeg2 Layer1 or AAC HE LC	Mpeg2 Layer1 or AAC HE LC	Identical
DICOM Support	System Supports	System Supports	Identical

10. Summary of Nonclinical Performance Testing

10.1 The following table summarizes the testing performed on the MedicVOD System to support this 510(k);

	mediCast Box (subject device)	mediCast Station (predicate device – K123426)	Comparison of subject device to predicate
Software Validation Testing	Software testing at the unit level	Software testing at the unit level. Additional nonclinical performance testing used to support K123426	Identical
Electrical Safety Testing	Testing performed to ensure compliance to IEC 60601-1 3rd Edition	Testing performed to ensure compliance to IEC 60601-1 3rd Edition	Identical
Electromagnetic Compatibility Testing	Testing performed to ensure compliance to IEC 60601-1-2:2007	Testing performed to ensure compliance to IEC 60601-1-2:2007	Identical
Emissions Testing	Tested to comply with FCC Part 15, Subpart B, Class B	Tested to comply with FCC Part 15, Subpart B, Class B	Identical

11. Summary of Clinical Performance Testing

11.1 No clinical testing was required to support the substantial equivalence to the predicate device.

12. Conclusion

12.1 Non-clinical verification and validation of the Orpheus Medical Ltd. MedicVOD System was performed through extensive bench testing. Results of the testing demonstrated that the Orpheus Medical Ltd. MedicVOD System design met all specifications and is adequate for its intended use. Additionally, the test results demonstrated substantial equivalence of the Orpheus Medical Ltd. MedicVOD System to its predicate device.

12.2 In conclusion, the Orpheus Medical Ltd. MedicVOD System is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the following legally marketed predicate device:

12.2.1 Orpheus Medical Ltd. MedicVOD System (K123426)