K112133

MAR - 1 2012

510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent:

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Submitter of 510(k):

Oasys Healthcare
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Date of Summary: February 2, 2012

Trade/Proprietary Name: OASYS Surgical Light Controller

K#: K112133

Classification Name: Class II

Product Code: FTA

Indications for Use:
The OASYS Surgical Light Controller allows the control of surgical lights during a procedure from the OASYS View user interface touch panel. It displays the status of the surgical light and controls the operation of the surgical light.

Device Description:
The OASYS Surgical Light Controller allows the control of surgical lights from the OASYS View user interface touch panel. It displays the status of the surgical light and controls the operation of the surgical light. It works with surgical lights from many vendors.

The OASYS Surgical Light Controller communicates with the target surgical light using serial or Ethernet communications. All communications include error and exception handling. The safety features and controls of the surgical light take precedence over these communications.

This software controlling the Surgical Light is written with C# and XML data structures that run on Windows Embedded 7. The software is an optional module

to the OASYS View OR Control application. OASYS View is a medical control application that allows for simple and streamlined management of an operating room. The software allows users to:

- Enable video routing from any source device to any destination device
- Preview selected sources on-screen
- Adjust image settings for video sources
- Change picture-in-picture capabilities on supported displays
- Control camera settings including:
- Panning & tilting
- Zooming
- Focusing
- Presets
- Operate medical-grade video recorders
- Select and listen to audio from an iPod or external audio device
- Engage in video conference calls

The software communicates with the light over a serial connection (RS485). Parameters are passed over a socket. The software manages the send and receive buffers to ensure effective communications. Data transmission is verified through the use of checksums and status commands.

The software allows for the Surgical Light to be initialized at run time. Default settings, such as brightness, are initialised on the Surgical Light. During normal operation, commands are passed back and forth based upon operator interaction with the graphical user interface. There are no patient contacting components.

Predicate Device:
EasySuite Surgical Light Control (K102791) software.

Substantial Equivalence:
The proposed OASYS Surgical Light Controller Software is substantially equivalent to Image Stream Medical - EasySuite Surgical Light Control (K102791). The proposed device has the same classification information, similar indications for use and function as compared to the predicate device.

Comparison between Proposed Device and Predicate Devices

Comparison Elements	**Applicant Device**	**Predicated Device**
Device Name	OASYS Surgical Light Controller Software K112133	EasySuite Surgical Light Control Software K102791
Classification Name	light, surgical, accessories	
Product Code	FTA	
Indications for Use	The OASYS Surgical Light Controller (software only) allows the control of surgical lights during a procedure from the OASYS View user interface touch panel. It displays the status of the surgical light and controls the operation of the surgical light.	EasySuite Light Control (ESLC) allows the control of surgical lighting during a surgical procedure from the EasySuite panel user interface
Level of Concern	Minor	
Patient Interaction	None	
Control Platform	Microsoft Windows 7 Embedded	Microsoft Windows Standard Embedded
Access	Touch Screen	
Function	Control of surgical lights from a convenient integrated operating room system. Control is defined by setting the light intensity or turning lights on and off.	
Calculations Performed	None	
Primary Control of Surgical Lights	The surgical light controls from the manufacturer take precedence over the OR control system.	
Primary Purpose of OR Control System	The OASYS OR Control System provides control of audio, video and environmental systems in the OR through a common user interface touch panel.	The system is primarily medical video image routing and communications system, which also controls functions such as ambient lighting.
Sterile Field	No components used in the sterile field.	
Comparison Statement	The applicant device has similar label and labeling as the predicate device.	
Comparison Analysis		
The applicant device has the same classification information, similar indications for use, and the same function, as the predicate device.		

Performance Testing:
Below is a summary of the performance testing was carried out on the OASYS Surgical Light Controller for integration of the user requirements and software requirements.

- Ability to increase brightness
- Ability to decrease brightness
- Ability to power ON the surgical light
- Ability to power OFF the surgical light.
- Ability to switch between surgical light mode(s)
- Ability to switch between surgical light feature(s)
- Ensure all communication happens within 5 seconds
- Test communications failure between the control system and surgical light controller
- Verify ability to connect Surgical Light Controller.
- Verify Communications
- Verify all other system connections
- Verify the device reboots properly

Conclusion Summary:
Comparison to the predicate devices listed shows nearly identical technical data, similar indications for use, and raises no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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MAR - 1 2012

Re: K112133
Trade/Device Name: OASYS Surgical Light Controller Software
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTA
Dated: February 23, 2012
Received: February 27, 2012

Dear Ms. O'Brien:

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.

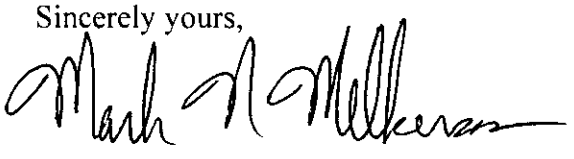
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112133

Device Name: OASYS Surgical Light Controller Software

The OASYS Surgical Light Controller Software allows the control of surgical lights during a procedure from the OASYS View user interface touch panel. It displays the status of the surgical light and controls the operation of the surgical light.

Prescription Use X *(Part 21 CFR 801 Subpart D)*	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112133