JAN - 7 2014

510(K) Summary

Date Prepared: 10/17/2013

510K Owner: Black Diamond Video
503 Canal Blvd
Richmond, CA94804

Contact: Ragunath Muniandy
Regulatory Affairs Specialist

Trade Name:	IDSS SLC
Common Name:	Surgical Light Control
Classification Name :	Light, Surgical Accessories
Classification Panel:	General and Plastic Surgery
CFR section:	21 CFR 878.4580
Class:	2
Product Code:	FTA
Predicate Device :	Easy Suite Surgical Light Control (K102791) OASYS Surgical Light Controller (K112133)
Device Description:	IDSS SLC is an additional function of the IDSS, which is an integrated operating room system that controls video displays, observation cameras, audio video equipment, teleconferencing and the routing of videos and images from multiple sources to multiple destination via touch screen interface.

Indications for use: IDSS SLC allows the control of surgical lighting during a surgical procedure from the IDSS, which is a centralized interface for voice, video, audio, observational camera and teleconferencing for the operating room.

Substantial Equivalence (SE) Rational: The IDSS SLC is substantially equivalent to predicate devices since intended use, operational principle, basic technology and design are similar. The minor differences between the IDSS SLC and predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended of use of the device. Therefore based on the applicable testing and the equivalence information presented in this submission, Black Diamond Video believes that IDSS SLC does not raise any new safety or efficacy issues.

Summary of Nonclinical Testing:
- Validation testing performed on interfaces, feature functional requirements, and non-function reliability.
- Electrical safety testing per EN 60601-1 and EN 60601-1-2:2007

Summary of Safety and Effectiveness: Testing and evaluation indicate that the system meets the needs of the users of the device and does not raise any new safety and efficacy of the predicate device. The IDSS conforms to the EN 60601-1 "Medical Electrical Equipment- Part 1-2 General requirement for safety.
EN 60601-1-2:2007 "Medical Electrical Equipment- Part 1-2 General requirement for safety- Collateral Standard: Electromagnetic compatibility- requirement and test.
CAN/CSA-C22.2 NO. 601.1 -Medical Electrical Equipment Part 1, General Requirements for Safety, Adopted IEC601-1 2ed(90)

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

Black Diamond Video Incorporated
Ragunath Muniandy
Regulatory Affairs Specialist
503 Canal Boulevard
Richmond, California 94804

January 7, 2014

Re: K133413
Trade/Device Name: IDSS SLC
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTA
Dated: October 17, 2013
Received: November 7, 2013

Dear Muniandy:

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 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. 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,

Joshua C. Nipper -S

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

Enclosure

Indications for Use

510(k) Number (if known): K133413

Device Name: IDSS SLC

Indications For Use:

IDSS SLC allows the control of surgical lighting during a surgical procedure from the IDSS, which is a centralized interface for voice, video, audio, observational camera and teleconferencing for the operating room.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—DIVISION SIGN-OFF

Division of Surgical Devices

510(k) Number: K133413

Long H. Chen -A

Digitally signed by Long H. Chen -A
Date: 2014.01.02 14:40:06 -05'00'