



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 1, 2016

Black Diamond Video, Inc.
Mr. Ragnath Muniandy
Regulatory Affairs Specialist
503 Canal Blvd
Richmond, California 94804

Re: K153205

Trade/Device Name: IDSS ForceTriad Control Module
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODA
Dated: June 27, 2016
Received: June 30, 2016

Dear Mr. 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 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,

Christopher J. Ronk -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)

K153205

Device Name

IDSS –ForceTriad Control Module

Indications for Use (Describe)

The IDSS-ForceTriad Control Module is designed for integration in the IDSS(Integrated Digital Surgical Suite) and enables the Covidien ForceTriad Energy Platform to be controlled remotely.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Date Prepared: 10/15/2015

510K Owner: Black Diamond Video

503 Canal Blvd

Richmond, CA94804

Contact: Ragunath Muniandy, RAC

Regulatory Affairs Specialist

Trade Name: IDSS –ForceTriad Control Module

Common Name: Endoscope and accessories

Classification Name: Endoscopic central control unit

Classification Panel: Gastroenterology/Urology

CFR section: 21 CFR 876.1500

Class: 2

Product Code: ODA

Predicate Device : Karl Storz SCB/Covidien ForceTriad Interface Module
(K111165)

Device Description: The IDSS ForceTriad Control Module is an additional function to the IDSS, which is an integrated operating room system controlling video displays, observation cameras, audio video equipment, teleconferencing and the routing of video and images from multiple sources to multiple destinations via a touch screen interface. With the IDSS ForceTriad Control Module, operation room staff is able to control the ForceTriad setup from the touch panel location rather than using the ForceTriad unit itself.

Indications for use: The IDSS-ForceTriad Control Module is designed for integration in the IDSS (Integrated Digital Surgical Suite) and enables the Covidien ForceTriad Energy Platform to be controlled remotely..

Substantial Equivalence

(SE) Rational: The IDSS –ForceTriad Control Module is substantially equivalent to the predicate device since intended use, operational principle, basic technology and design are similar. The minor differences between the IDSS –ForceTriad Control Module and the predicate device 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 –ForceTriad Control Module does not raise any new safety or efficacy issues.

Summary of Nonclinical

Testing: - Software Verification and Validation testing were performed on interfaces, feature functional requirements, and non-functional reliability. The software validation activities were performed in accordance with the FDA Guidance “Guidance for the content of premarket Submissions for Software Contained in Medical Devices”. The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007.

Conclusion: 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.