ConVida Healthcare & Systems

JUN 0 9 2014

Integrate Visual Clarity at the Highest Precision

510(K) Summary

1. **Type of Submission:** Traditional
2. **Preparation Date:** April 3, 2014
3. **Revised Date:** N/A
4. **Submitter:** ConVida Healthcare & Systems Corporation

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   Contact: Sharon Lee / Regulatory Engineer

   Registration Number: 3010402711

5. **Identification of the Device:**

   Proprietary/Trade name: VIDA LED Surgical Lighting System, V series

   Common Name: Surgical lamp

   Classification Name: Light, Surgical, Ceiling Mounted

   Device Classification: 2

   Regulation Number: 878.4580

   Panel: General & Plastic Surgery

   Product Code: FSY

6. **Identification of the Predicate Device:**

   Predicate Device Name: VIDA LED Surgical Lighting System-X series

   Manufacturer: **ConVida Healthcare & Systems Corporation**

   Product Code: FSY

   510(K) Number: K132307

7. Intended Use and Indications for Use of the Subject Device:

Intended Use:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

Indications for Use:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

8. Device Description:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

VIDA LED Surgical Lighting System, V series uses high-efficacy light-emitting-diodes (LED) as light source which provides high brightness and no extra heat; the design of the optical mechanism gives a characteristic of less shadow which is significant to the surgeon during the operation. Given of its modular design, VIDA V provided many options for configurations and can be installed in an operating room with or without a laminar air flow system.

The features of VIDA LED Surgical Lighting System, V series are as followed:

- **Prism-Based Light Delivery Technology:** ConVida's patented optical system, that combines an advanced refractive prism lens and innovative high-power LED technology, focuses light into an intense 110cm (43") focal cylinder, eliminating the need for refocusing when adjusting surgical table.
- **Consistent Illumination at Different Color Temperature Settings:** VIDA V series lighthead's color temperature can be individually adjusted at any of the 5 settings (3500K, 4000K, 4250K, 4500K, 5000K) with a high CRI of 95, R9 94.
- **Optimal Brightness without Glare:** Elegant, sophisticated optical system consists up to 2 types of high-power LEDs and multiple refractive prisms produces up to 160,000 lux of intensity without discomfort flare/glare.
- **VIDA V light gives the Surgeon Control:** On the VIDA V, both lighthead focus and light intensity can easily be adjusted via turning the lighthead handle. They are also adjustable from the standard lighthead control or optional VIDA V Control Center on the wall.
- **Long Lifetime:** Under normal use, VIDA V LEDs enjoy an extremely long lifetime of 50,000+ hours (70% lumen maintenance at 50,000 hours).
- **Two Types of Ambient Lights (Option):** 5% central luminance (GUIDE lighting mode) can be configured through standard lighthead control. Guide lighting mode may be used as ambient lighting for manipulating endoscopy instruments or lighting diagnostic procedures. Green ambient light sheds low-level green light from the suspension hub.

and is controllable on the optional VIDA V Control Center.

- **Camera-Ready Lighthead is Built into the System:** All VIDA V lightheads are pre-wired with HD cabling for taking an optional HD 1080p Camera Handle. The HD 1080p Camera Handle is removable from one VIDA V lighthead to another providing superb flexibility for recording.
- **Exceptional Maneuvering Flexibility:** The exceptionally durable non-sterile handles allow easy positioning of all our lightheads. Each lighthead rotates a full 360°so that the system can be quickly and easily positioned for any surgical procedure. Individual lightheads can be lower to 810mm above the floor providing excellent low lateral illumination.
- **Sleek Non-Sterile Handle**: The lighthead has is molded with a sleek all-around handle that facilitates easy repositioning and adds modern elegance to O.R. setting
- **Easy-to-clean Compact Lighthead**: Made of tough molded materials, the VIDA V series lightheads are completely sealed which helps prevent biocontaminants from entering the operative site and lighthead itself, and facilitates cleaning.
- **HD Supported Suspensions**: All VIDA V suspensions are prewired with video cables to deliver information users need within and without the surgical field. Images are in crisp and accurate HD format with no signal conversion necessary and no loss of video quality.
- **Heavy Duty HD Flat Monitor Suspension:** Flat Monitor Suspension Arms support single/dual monitors up to a total of 24 kg (53 lbs), making them ideal for surgical displays up to 32". Large display compatibility allows the surgical team to see more of the procedural area. Optional Medical Grade LCD Displays from SONY also offer uncompressed HD video at 1080p which shows true images from SD- and HD-endoscopes, ultrasound, C-arms and other equipment.
- **Optimal HD Connectivity:** The built-in fiber optic cable allows the suspension to support monitors featuring Full HD 1920 x 1080 video signals.
- **Low Profile Suspension**: Low-profile cardinal lighthead suspension is offered for rooms with ceiling lower than 280mm.
- **Failsafe Design:** The unit is protected against an electrical power failure, thus ensuring that all surgical procedures can continue without interruption.

9. Performance Summary:

This device conforms to the standards listed as below:

- IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-2-41:2009 Medical Electrical Equipment – Part 2-41: Particular requirements for the basic and essential performance of surgical luminaires and luminaires for diagnosis
- IEC 60601-1-2:2007 Medical Electrical Equipment, Part 1-2: General requirements for basic Safety and essential performance Collateral Standard: Electromagnetic Compatibility Requirements and tests
- IEC 62304:2006 Medical Device Software: Software Life Cycle Process
- ISO 14971:2007 Medical Device: Application of Risk Management to Medical Devices
- ISO 15223-1:2012 Medical Device: Symbols to be used with medical device labels, labeling and information to be supplied, part 1: General requirements
- ISO 17664:2004 Sterilization of medical devices: information to be provided by the manufacturer for the processing of resterilizable medical devices
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10. Safety and Effectiveness

The bench testing result shows that the proposed device is complied with IEC standards, and as safe as the predicate device.

11. Substantial Equivalence Determination:

The VIDA LED Surgical Lighting System, V series is substantially equivalent to VIDA LED Surgical System-X series. There are no negative effect on safety or effectiveness between VIDA LED Surgical Lighting System, V series and the predicate device. The following is the detail of the compared item.

	Proposed Device		Predicate Device	
Item	The VIDA LED Surgical Lighting System, V series		The VIDA LED Surgical Lighting System-X series	
Manufacturer	ConVida Healthcare & Systems Corp.		ConVida Healthcare & Systems Corp.	
Classification	Class II		Class II	
Regulation Number	878.4580		878.4580	
Product Code	FSY		FSY	
Intended Use	The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.		VIDA LED Surgical Lighting System- X series provide illumination for surgery or examination at operating room.	
Lighthead model	V70	V50	X70	X50
Similarity				
Over-the-counter Medical Device	No		No	
Light Source	LED	LED	LED	LED
Color Rendering Index (CRI)	95	95	95	95
LED Life time (hrs)	50,000	50,000	50,000	50,000
Difference				
Diameter of Light Head (cm)	82	72	72	58
Number of LEDs	55	44	90	60
Central illumination (at 1m) (lux)	160,000	140,000	160,000	130,000
Color temperature, Kelvins	3500-5000K (3500K, 4000K, 4250K, 4500K, 5000K)	3500-5000K (3500K, 4000K, 4250K, 4500K, 5000K)	4200	4200
Total irradiance (W/m^2)	592	518	< 656	≤533
Irradiance intensity (mW/m^2lux)	3.7	3.7	4.1	4.1

d_{50}/d_{10} (%)	56	59	> 50	> 50
Light field size, d_{10} (cm)	17~30	16~27	20~32	18~28
Depth of illumination L1+L2 (cm)	20%: 110 60%: 45	20%: 100 60%: 45	20%: 140 60%: 71	20%: 145 60%: 82
Power Consumption	100W@24Vdc	100@24Vdc	100W	80W

12. Non-clinical Performance Testing:

Performance testing were conducted to verify that the VIDA LED Surgical Lighting System, V series meets the requirements for Medical Electrical Equipment as defined in IEC 60601-1, IEC60601-2-41, and IEC 60601-1-2

13. Clinical Performance Testing:

No Clinical testing is required for this device classification submission.

14. Conclusion:

The VIDA LED Surgical Lighting System, V series submitted in this 510(K) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared VIDA LED Surgical Lighting System-X series which is the subject of K132307. Differences between the devices cited in this section do not raise any new issue of safety or effectiveness. After analyzing bench test, safety testing data, it can be concluded that VIDA LED Surgical Lighting System, V series is substantially equivalent to the predicate device.

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

June 9, 2014

ConVida Healthcare & Systems Corporation
Sharon Lee, Regulatory Engineer
No. 33, Dinghu Road
Guishan Township,
Taoyuan County 33378, Taiwan

Re: K140930
Trade/Device Name: VIDA LED Surgical Lighting System, V Series
Regulation Number: 21 CFR 878.4580
Regulatory Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: April 09, 2014
Received: April 11, 2014

Dear Ms. Lee:

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" (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 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,

David Krause -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

cc: DMC
510(k) Staff
Division
D.O.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140930

Device Name
VIDA LED Surgical Lighting System, V series

Indications for Use *(Describe)*
The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

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)*

Neil R Ogden -S
2014.06.05 15:06:29 -04'00'

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