510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Preparation Date:** July 19, 2013

NOV 0 5 2013

5.3 **Revised Date:** N/A

5.4 **Submitter:** CONVIDA HEALTHCARE & SYSTEMS CORPORATION

Address: 2F and B2., No.33, Dinghu Rd., Guishan Township, Taoyuan County, Taiwan

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Contact: Ryan Hung / Regulatory Engineer

Establishment Registration Number: N/A

5.5 **Identification of the Device:**

Proprietary/Trade name:	VIDA LED Surgical Lighting System-X 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

5.6 **Identification of the Predicate Device:**

Predicate Device Name:	Mach LED SC
Manufacturer:	Dr. Mach GmbH& Co.KG
510(k) Number or Clearance Information:	K093009

5.7 **Intended Use and Indications for Use of the subject device.**

Intended Use: VIDA LED Surgical Lighting System – X series provide illumination for surgery or examination at operating room.

Indications for Use: VIDA LED Surgical Lighting System-X series provide illumination for surgery or examination at operating room.

5.8 Device Description

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

The VIDA LED Surgical Lighting System-X series (VIDA X) use high-efficacy light-emitting diodes (LED) for surgical operations and diagnostic purposes. LEDs provide bright and shadow reduced light. Thanks to its modular design, VIDA X also offers many options for configurations and can be installed in operating rooms with or without laminar air flow systems.

A lighthead to the main spindle can be rotated horizontally with 360°, the spring arms can be rotated horizontally with 360° and moved vertically with 45° downwards and 30° upwards.

The VIDA LED Surgical Lighting System-X series consists of Mounting Module, Horizontal Arm module, Suspension Device Module, sterile handle cover and Optional Accessories.

Optional accessories for the VIDA LED Surgical Lighting System-X series are as follows:

---- Sterile Handle Cover (for the X50 and X70 lighthead which doesn't mount the Camera, XV, S12, S15 and D24 suspensions.)

---- Camera Handle module (1080p) (which can be installed on X50 or X70 lighthead or XV suspension.)

---- Medical Grade Flat Monitor

---- Fiber Optic Coder/Decoder Set (including fiber optic transmitter and receptor)

5.9 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

5.10 Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

5.11 Substantial Equivalence Determination

The VIDA LED Surgical Lighting System-X series is substantially equivalent to Mach LED SC. Any difference that exists between the Mach LED SC and the predicate device has no negative effect on safety or effectiveness and actually enhances the usefulness in the chosen application.

Item	Proposed Device VIDA LED Surgical Lighting System-X series (CONVIDA HEALTHCARE & SYSTEMS CORPORATION)		Predicate Device Mach LED SC (Dr. Mach GmbH& Co.KG, K093009)	
Classification	Class II		Class II	
Code or Federal Regulations	878.4580		878.4580	
Intended Use	VIDA LED Surgical Lighting System – X series provide illumination for surgery or examination at operating room.		The Mach LED SC lighting system is designed for illuminating an examination area and surgical field at the hospital and doctor's practice.	
	X70	X50	5sc	3sc
Similarity				
Over-the-counter Medical Devices	No		No	
Light Source	LED	LED	LED	LED
Color Rendering Index	95	95	95	95
Central illumination (at 1m) (lux)	160,000	130,000	160,000	130,000
Input Power	100-240V, single phase, 50-60Hz		-	

Difference				
Diameter of Light Head	72cm	58cm	72cm	57cm
Number of LEDs	90	60	40	28
Lighthead Wattage	150W	120W	-	-
Power Consumption	100W	80W	65W	45W
Color temperature (Kelvin)	4200	4200	4500°K	4500°K
Light field diameter	D10: 20~32cm D50/D10: >50%	D10: 18~28cm D50/D10: >50%	20~32cm	17~28cm
Depth of illumination	L1+L2 20%: 140cm	L1+L2 20%: 145cm	-	-
	L1+L2 60%: 71cm	L1+L2 60%: 82cm		
Total irradiance at maximum intensity	<656W/m²	<533W/m²	-	-
Average LED Life time(hours)	50,000	50,000	>40,000	>40,000
Light focusing mechanism	Manual focusing	Manual focusing	-	-
Ultraviolet light filter mechanism	NA	NA	-	-
Available accessories	Standard accessories: -Sterile Handle Cover x2 (X50, X70, XV, S12, S15) -Sterile Handle Cover x4 (D24) Optional Accessories: -Sterile Handle Cover (for the X50 and X70 lighthead which doesn't mount the Camera, XV, S12, S15 and D24 suspensions.) -Camera Handle module (1080p) (which can be installed on X50 or X70 lighthead or XV suspension.) -Medical Grade Flat Monitor -Fiber Optic Coder/Decoder		-Camera module -Remote control for camera module -Remote control with network interface for camera module -Single monitor yoke for flat panel monitors -Double monitor yoke for flat panel monitors -Instrument trays -Trays for CRT monitors -24V DC battery backup support -Low profile wall control unit -Integrated laser pointer	

	Set (including fiber optic transmitter and receptor)	-Sterilizable handle sleeves

5.12 Non-clinical Performance Testing

Performance testings were conducted to verify that the VIDA LED Surgical Lighting System-X series meet the requirements for Medical Electrical Equipment as defined in IEC 60601-1, IEC 60601-2-42, and IEC 60601-1-2.

5.13 Clinical Performance Testing

No clinical testing is required for this device classification submission.

5.14 Conclusion

The VIDA LED Surgical Lighting System-X series submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Mach LED SC which is the subject of K093009. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness. After analyzing bench tests, safety testing data, it can be concluded that VIDA LED Surgical Lighting System-X 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

CONVIDA HEALTHCARE & SYSTEMS COPRORATION November 5, 2013
Mr. Ryan Hung
Regulatory Engineer
2F and B2., No.33, Dinghu Road., Guishan Township
Taoyuan County
Taiwan 33378

Re: K132307
Trade/Device Name: VIDA LED Surgical Lighting System-X series
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: September 18, 2013
Received: September 19, 2013

Dear Mr. Hung:

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,

Mark N. Melkerson -S

Mark N. Melkerson
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): K132307

Device Name: VIDA LED Surgical Lighting System-X series

Indications for Use:

VIDA LED Surgical Lighting System – X series provide illumination for surgery or examination at operating room.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.11.05 14:37:11 -05'00'

for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132307