K131893

510(k) SUMMARY
(as required by 807.92)

OCT 3 0 2013

Regulatory Correspondent:

AJW Technology Consultants, Inc.
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Apollo Beach, FL 33572 USA
Janet Douglas
Email: jdouglas@ajwtech.com

Submitter of 510(k):

Amico Clinical Solutions Corporation
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Richmond Hill, ON L4B 2N4 Canada
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Date of Summary: September 17, 2013

Trade/Proprietary Name: Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights

Common/Usual Name: Surgical Lamp

Classification Name: Class II

Product Code: FSY

Intended Use:

Device Name: Amico iCE LED Light
The intended use of the Amico iCE LED series surgical lights are to provide high intensity, shadow free illumination to the patient surgical field during surgical procedures.

Device Name: Amico Mira LED Series Minor Surgical Light
The intended use of the Amico Mira LED series minor surgery lights is to provide high intensity, shadow free illumination to the patient surgical field during minor surgery procedures.

Device Description:

Amico iCE Series Device Description:
Amico iCE series consists of 3 models – iCE-30-6, iCE-25-6, & iCE-25-3. These are major surgical luminaires that provide illumination in a surgical suite allowing doctors to operate on a patient.. The device comes with several built-in fail safe's preventing any single fault from creating a hazardous situation.

These lamps are a Class 2 device (under FDA) providing max illumination of 160,000 lx, 160,000lx, and 130,000 lx respectively. These surgical lights are coupled with ceiling mounted suspension systems supporting horizontally articulating extensions arms and horizontally and vertically articulating spring arms. Both arms can rotate either 340 degree (with stop) or infinitely without a stop. The spring arms vertically articulate 50^0 downwards and 45^0 upwards. This allows for ease of movement of the lamp head to any given position.

The lamp housing is made of high quality plastic wrapped around an aluminum structure. The front clear glass is made of high quality polycarbonate material. The yoke connecting the lamp head to the spring arms is made of steel.

The lamps also have a built-in mechanical focusing system that is controlled using the center Aluminum and/or plastic handle. Rotating this handle allows the user to expand and contract the lighted field as per the user's requirement. The lamps can also be sold with an optional in-light camera that doubles as a focusing handle. This provides the user with the option to record/display small areas of a surgical site on a large display allowing for greater detail and accuracy during surgeries. A separate remote control is used to control the various functions of the camera.

Available accessories for iCE series surgical lights

- 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
- Low profile wall control unit

Amico Mira LED Series Device Description:
Amico Mira LED series consists of 3 models – Mira LED 90, Mira LED 65 & Mira LED 50. These are minor surgical luminaires that provide illumination in a surgical suite allowing doctors to perform minor surgical procedures on a patient.
These lamps are a Class 2 device (under FDA) providing max illumination of 90,000 lx, 65,000 lx, and 50,000 lx respectively. These surgical lights are coupled with ceiling

mounted suspension systems supporting horizontally articulating extensions arms and horizontally and vertically articulating spring arms. Both arms can rotate either 340 degree (with stop) or infinitely without a stop. The spring arms vertically articulate 50^0 downwards and 45^0 upwards. This allows for ease of movement of the lamp head to any given position.

The lamp housing is made of high quality plastic which connects to the yoke. The front clear glass is made of high quality polycarbonate material. The yoke connecting the lamp head to the spring arms is made of steel.

The lamps also have a built-in electronic focusing system that is controlled using the center Aluminum/plastic handle. Rotating this handle allows the user to expand and contract the lighted field as per the user's requirement.

Predicate Device: K093009 Mach LED SC
K093010 Mach LED MC

Substantial Equivalence:
The Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights are substantially equivalent in intended use and technological characteristics to the Mach LED SC and Mach LED MC surgical lights. Any difference that exists between the Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights and both predicate devices has no negative effect on safety or effectiveness.

Comparison of Technological Characteristics				
Comparison Elements	**Applicant Device**	**Applicant Device**	**Predicated Device**	**Predicated Device**
510(k) Number			K093010	K093009
Device Name	Amico iCE LED	Amico Mira LED	Mach LED MC	Mach LED SC
Technical Data				
Light Intensity (Central Luminance)	130,000 - 160,000	50,000 - 90,000	160,000	130,000
Color Rendering Index (Ra)	95	95	≥ 96	95
Color rendering index R9(red)	>90	95	95	95
Focusable size of the light field	7.6-12.0in	7.0-12.0in	17-28cm	17-28cm

Comparison of Technological Characteristics				
Comparison Elements	**Applicant Device**	**Applicant Device**	**Predicated Device**	**Predicated Device**
510(k) Number			K093010	K093009
Device Name	Amico iCE LED	Amico Mira LED	Mach LED MC	Mach LED SC
Color temperature (Kelvin)	4500K	4500K	3750, 4000, 4250, 4500, 4750	4500K
Diameter of the lamp head	25-30in	18in	57cm	57cm
Total power consumption	150-200	75	120 W	45 W
Brightness Control	5-100%	5-100%	5-100%	5-100%
# of other LED's	208-320	144	112	28
LED service life	50,000	50,000	> 40.000 h	> 40.000 h
Mounting Options	Ceiling, Wall,	Ceiling, Wall, Roll Stand	Ceiling, Wall, Roll Stand	Ceiling, Wall, Roll Stand

Sterilization and Shelf-Life

The Disposable Light Handle (K020304) is used as an accessory to the Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights. The Disposable Light Handle provides a sterile interface between the Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights, and the Surgeon or Scrub Nurse.

Non-Clinical Testing:

Electrical Safety testing was carried out on the Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights. Below is a summary of the performed testing:

Attachment A: IEC 60601-1 Medical electrical equipment
Part 1: General requirements for basic safety and essential performance
Report Reference No.: 100874632MTL-002
Result: Pass
Attachment B: IEC 60601-2-41 Medical electrical equipment
Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
Report Reference No.: 100874632MTL-003
Result: Pass
Attachment C: Constructional Data Report

Report Reference No.: 100874632MTL-001
Result: Pass

Attachment D: IEC 60601-1-2 (Ed. 3): 2007 - Medical electrical equipment Part 1-2:General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Report Reference No.: 100874632ATL-003
Result: Pass

Attachment E: IEC 60601-1-2 (Ed. 3): 2007 - Medical electrical equipment Part 1-2:General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Report Reference No.: 100874632ATL-004
Result: Pass

Electrical Safety Testing Conclusions:

Based on the performed testing it has been shown that Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights has been proven to be safe and effective and poses no foreseen hazards. No Open Items remain from the planned Amico Clinical Solutions Corp. - iCE LED Series and Amico Lights Corp. - Mira LED Series Minor Surgical Lights Electrical Safety Testing.

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

Amico Clinical Solutions Corporation
% Ms. Janet Douglas
AJW Technology Consultants, Incorporated
445 Apollo Beach Boulevard
Apollo Beach, Florida 33572

October 30, 2013

Re: K131893
Trade/Device Name: Amico iCE LED Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: September 17, 2013
Received: September 27, 2013

Dear Ms. Douglas:

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): K131893

Device Name: Amico iCE LED Light

The intended use of the Amico iCE LED series surgical lights are to provide high intensity, shadow free illumination to the patient surgical field during surgical procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131893

Indications for Use

510(k) Number (if known): K131893

Device Name: Amico Mira LED Series Minor Surgical Light

The intended use of the Amico Mira LED series minor surgery lights is to provide high intensity, shadow free illumination to the patient surgical field during minor surgery procedures

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)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: cn=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003691056 Date: 2013.10.29 13:52:16 -04'00' for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131893