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

August 22, 2014

Dr. Mach GmbH & Company KG
% Gudrun Busch, Ph.D.
Dr. Busch Regulatory Strategy GmbH
Fehmarnstrasse 31
Norderstedt, Schleswig-Holstein 22846
Germany

Re: K140461
Trade/Device Name: Mach LED 2MC
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: FSY
Dated: February 27, 2014
Received: March 5, 2014

Dear Dr. Busch:

This letter corrects our substantially equivalent letter of April 3, 2014.

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

Enclosure

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 on last page.

510(k) Number *(if known)*
K140461

Device Name
Mach LED 2MC

Indications for Use *(Describe)*
The surgical light Mach LED 2MC is intended to illuminate the operating site on the patient's body with a high intensity, shadow-free and "cold" light.

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)*

Joshua C. Nipper -S

K140461

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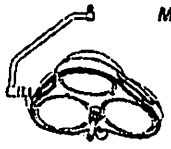
Medizinische Leuchten + Technik



APR 0 9 2014

510(k) Summary for Mach LED 2MC

as required by section 807.92(c)

Submitter	Dr. Mach GmbH & Co.KG Flossmannstrasse 28 85560 Ebersberg Germany
Contact Person	Rainer Adams Technical Director Phone: +49 8092 209330 Fax: +49 8092 209350
Preparation Date	February 14, 2014
Trade Name	Mach LED 2MC
Common Name	Surgical Lamp
Classification Name	Surgical Lamp Regulation 21 CFR 878.4580, Class II Product Code: FSY
Predicate Device	Mach LED MC Surgical lamp 510(k) No. K093010, April 1, 2010

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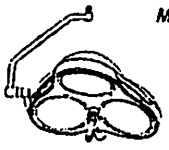

Device Description

The surgical light Mach LED 2MC is intended to illuminate the operation site on the patient's body with a high intensity, shadow free and "cold" light.

The Mach LED 2MC consists of lamp housing, LED modules, optical, electrical and mechanical components, one sterilizable handle sleeve as well as the cables.

One LED-module consists of 4 different-colored LEDs: warm white, cold white, green and red. The four different colors are merged inside the lamp head by a computer-calculated optical system with light guide and facetted lenses.

The light system can be added to the ceiling mounted suspension system supporting the horizontal arms and spring arms. The horizontal arms can be rotated horizontally with 360°, the spring arms can be rotated horizontally with 360° and moved vertically with 50° downwards and 45° upwards.

The light system is operated by a keypad on the lamp head or, by special request of the customer, by a keypad on the wall.

The surgical light Mach LED 2MC will be marketed with merging of light fields, light intensity control, color temperature adjustment and integrated laser pointer.

Available accessories for the Mach LED 2MC lighting systems are as follows:

- Camera module
- Remote control of 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
- Sterilizable handle sleeves

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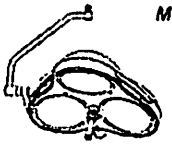

Intended Use

The Mach LED 2MC lighting system is designed for illuminating an examination area and surgical field at the hospital and doctor's practice.

The intended use is identical to the intended use of the predicate device Mach LED MC, K093010.

Technological characteristics Comparison

The Mach LED 2MC has the same technological characteristics (design, materials, chemical composition, energy source) as the predicate device. The Mach LED 2MC and the predicate device Mach LED MC are both based on the LED (light-emitting diode) technology.

For the new device, the number of LEDs was reduced. Therefore, dimensions of the light head diameter, the illumination depth, and the light intensity have been reduced accordingly.

Technical Parameter	New Device	Predicate Devices	
	Mach LED 2MC	Mach LED 3MC	Mach LED 5MC
Number of LEDs	84	112	160

Non-clinical data

Performance testing was conducted to verify that Mach LED 2MC meet the requirements for Medical Electrical Equipment as defined in the relevant standards for Medical electrical equipment and the EN 61000 group.

The accessories are identical to those used with the predicate device.

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification test methods used are the same as those submitted for the predicate device submission.

Clinical data

No clinical data is required for this device classification submission.

Conclusions

The modifications incorporated into the Mach LED 2MC design are minor (change in number of LEDs). Based on the information provided herein it is concluded from the performed testing that the device is as safe, as effective, and performs as well as the predicate devices.