K093010 Pg 1 of 2

Dr. Mach
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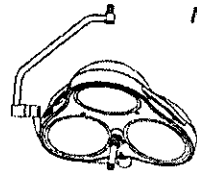

5.0 Traditional 510(k) Summary

Submitter: Dr. Mach GmbH & Co.KG
Flossmanstraße 28
85560 Ebersberg
Germany

APR - 1 2010

Contact Person: Rainer Adams
Technical Director
Phone: +49 (0)8092-209330
Fax: +49 (0)8092-209330

Preparation Date: July 13, 2009

Trade Name: Mach LED MC

Regulation Number: 21 CFR 878.4580

Regulation Name: Surgical Lamp

Regulatory Class: Class II

Product Code: FSY

Device Description:

The surgical light Mach LED MC is intended to illuminate the operating site on the patient's body with a high intensity, shadow-free and "cold" light.
This 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 Mach LED MC 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-coloured LED's: warm white, cold white, green and red. The four different colours are merged inside the lamphead by a computer-calculated optical system with light guide and facetted lenses.
The surgical light Mach LED MC will be market with merging of light fields, light intensity control, colour temperature adjustment and integrated laser pointer.
Available accessories for the Mach LED MC lighting systems are as follows:

- 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

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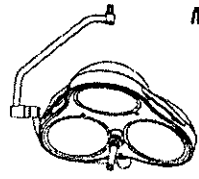

- Trays for CRT monitors
- 24V DC battery backup support
- Low profile wall control unit
- Sterilizable handle sleeves

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

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

Predicate Device:
iLED (K061317), Trumpf Kreuzer Medizin System GmbH

Substantial Equivalence:
The Mach LED MC is substantially equivalent to the surgical light iLED. Any difference that exists between the iLED and the Mach LED MC has no negative effect on safety or effectiveness and actually enhances the usefulness in the choosen application.

Technological Characteristics Comparison:
Technological Characteristics of Subject Device are based on the same LED (light-emitting diode) technology as the Predicate Device. For detailed comparison of all functionalities of the subject device and the predicate devices refer to Chapt.12: Substantial Equivalent discussion.

Discussion according non-clinical performance data testing:
Performance testing was conducted to verify that Mach LED MC meet the requirements for Medical Electrical Equipment as defined in EN 60601-1, EN 60601-2-42, EN 55015 and EN 61000-4.

Discussion according clinical performance data testing:
No clinical data is required for this device classification submission.

Test Conclusions of non-clinical data:
Testing was performed according to external procedures. Performance testing and validation were done at TÜV SÜD Product Service and mikes-testingpartners GmbH. Please refer to Chapter 18 and Appendic C.

Dr. Hans-Jorg Kemper
General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Dr. Mach GmbH & Co. KG
% Rainer Adams
Technical Director
Flossmannstrasse 28
85560 Ebersberg, Germany

APR - 1 2010

Re: K093010
Trade/Device Name: Mach LED MC
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: March 10, 2010
Received: March 30, 2010

Dear Rainer Adams:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

pg 1 of 1

510(k) Number (if known): K093010

Device Name: Mach LED MC

Indications for Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093010