K091246

5. 510 (k) Summary

SEP 2 8 2009

Submitter: TRUMPF Medizin Systeme GmbH + Co. KG
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Preparation Date: April 16, 2009

Trade Name: iLED Surgical Family, Mobile

Common Name: Surgical lamp, Mobile

Classification Name: Surgical Lamp

Device Description: The iLED surgical light mobile family is suitable for all types of surgical procedures.

TruLight 5000 light heads consists of two light modules and the iLED 3 consists of three light modules. The modules contain the LEDs with their optical devices. Each LED with its optical device illuminates the complete light field. Each light module has its own control to adjust the illumination parameters.

The light heads operate the same and use the same electronics and software as the ceiling mounted iLED family surgical light systems.

Intended Use of the Device	The iLED surgical light mobile family is for illuminating an examination and surgical site on the patient in the clinic and doctor's office.
Indication for use:	The iLED surgical lamps illuminate the surgical site with a high intensity, homogenous light.
Predicate Device:	iLED (lamp heads are identical) K# 061317 Trumpf surgical light models 301, 501, 701, and 1001 (mobile stand option was included) K # 011693
Substantial Equivalence:	The iLED surgical light mobile family had identical lamp heads as the iLED surgical light ceiling mounted versions. The iLED surgical light mobile family uses the same spring arm as the ceiling mounted version and same electronics as the ceiling mounted version. The mobile family is substantially equivalent to the mobile stand approved in K #011693 and other mobile surgical light systems. There is no difference between the devices that raise any significant issues of safety and effectiveness.
Main Difference:	The method of mounting the spring arm is the main difference from the iLED surgical light ceiling mounted, the unit is made mobile. The spring arm for the unit is mounted to a mobile stand with a base and 4 casters and plugs into an outlet. The main difference from the mobiles included in K # 011693 is the light heads, which are LED light heads (identical to those sold as ceiling mounted per K#061317).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

TRUMPF Medizin Systeme GmbH + Co. KG
% TRUMPF Medical Systems, Inc.
Ms. Lindsey Hengel
415 Jessen Lane
Charleston, South Carolina 29492

SEP 2 8 2009

Re: K091246
Trade/Device Name: Surgical Lamp Mobile
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSS
Dated: September 15, 2009
Received: September 16, 2009

Dear Ms. Hengel:

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.

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.

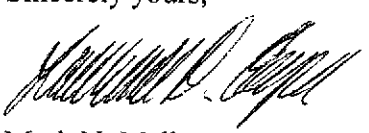
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



FOR 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 Form (Text Version)

Indications for Use

510(k) Number (if known): K091246

Device Name: Surgical Lamp Mobile

Indications for Use: The surgical light family is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "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 M. MELKERSON

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

510(k) Number K091246