K102758

E. 510 (k) Summary

OCT 2 6 2010

Submitter:	TRUMPF Medizin Systeme GmbH + Co. KG Benzstraße 26 82178 Puchheim Germany
Contact Person:	Lindsey Ronneberg Quality Manager, TRUMPF Medical Systems, Inc. Phone: 843-416-1376 Fax: 843-534-0206
Preparation Date:	September 8, 2010
Trade Name:	Surgical Light, TruLight
Common Name:	Surgical light, Ceiling Mounted
Classification Name:	Surgical Lamp
Product Code:	FSY
Device Relationships:	TRUMPF Medical Systems, Inc. distributes "Surgical light, Ceiling Mounted, ILED" systems cleared under K061317 with one to three arms per suspension. The devices are offered in a variety of combinations of the approved light heads. The light heads contain two to five modules each containing LEDs. The "ILED X" family of light heads will be transitioned to names involving "TruLight XXXX" over the next several years. The most complex of the ILED light heads is the ILED 5. The ILED 5 offers adjustable color temperature, dimming, focus, and shadow control. TRUMPF Medical Systems, Inc. released the next versions of light heads including the TruLight 5500 and 5300 in 2009. These light heads in addition to the ILED 3 and ILED 5 are offered on the same suspension system as the "Surgical light, Ceiling Mounted, ILED". The TruLight 5500, 5300, and ILED 3 light heads are offered on a mobile stand as well. They are known as "Surgical Lamp Mobile". The mobile systems with the three light head options were cleared under K091246. TRUMPF completed a letter to file stating that the TruLight 5500 and 5300 light heads offered on a ceiling mounted system (same mounting as the original ILED family light heads) did not require a 510K because there is no significant change from the cleared devices and there was no altering of the device's safety or effectiveness.

II SU

TRUMPF Medical Systems, Inc. listed a surgical light Helion 501 and 701 cleared under K011693. This light was available with a laser focus feature. The laser was a Class 2 laser and it was an optional feature on the Helion light systems. This item is primarily listed as a predicated device due to its use of a laser for assistance with the focusing of the device (similar to the ALC+ feature).

Details of the predicated devices in comparison to the new devices are provided in pages 5 and 6 of this section.

Device Description:

TruLight 5520 and 5320 light heads consist of 2 light modules containing LEDs which illuminate the area of a patient. The light heads are equipped with illuminated non-sterile hand grips. The light heads can be controlled on the control panel on the light head or on an optional wall control panel. Illuminance can be adjusted between 30 and 100%. Reducing the Illuminance does not change the color temperature of the light. The illuminance can also be adjusted to "endo" mode, which is 5%.

The optional Adaptive Light Control (ALC) feature allows the lighting settings to be selectively adjusted to the working distance. The three settings for a working distance of approx. 0.8, 1.0 and 1.2 meters are selected on the control panel or on the wall control panel. The light head then selects the light setting suitable for this working distance.

The Adaptive Light Control Plus (ALC+) offers automatic control of the light intensity. If the light head is moved during surgery, the motion detection function automatically measures the distance between the luminaire and the wound area. The light head then selects the light setting suitable for this working distance.

Intended Use:

The surgical light family is for illuminating an examination and surgical site on the patient in the clinic and doctor's office.

Indication for use:

The TRUMPF surgical lights are intended to locally illuminate an operating or examination area of the patient's body with high intensity light.

Predicate Device:

Light Surgical Ceiling Mounted, iLED
K# 061317

Surgical Lamp, Mobile
K# 019246

TRUMPF Surgical Lights, Models 501 and 701
K# 011693

Substantial Equivalence: Please see the Substantial Equivalence tables in page 5 and 6 of this section to review the technical details and applications of the predicated and new devices. The main difference is identified here.

The Main Difference:
The difference from the predicated TL5500 and 5300 is the addition of the Adaptive Light Control Plus (ALC+) option. Lighting systems prepared with the ALC+ option still have the original ALC control system of the TruLight 5500 and 5300. The ALC+ system can be activated and deactivated by the user pressing the left and right ALC symbols on their control panels. Therefore, the light can operate identically to the predicated TruLight 5500 and 5300 light heads.

Testing to the standards mentioned, risk analysis, and comparison to devices with lasers similar to that of the ALC+ have verified the new device is not any less safe or effective than the predicated devices.

Sterilization:

Reusable sterile handle grips are instructed to be sterilized by traditional moist heat sterilization with the following instructions:

Steam sterilization: The hand grips can withstand at least 350 steam sterilization cycles without damage under the following criteria:

- Steam sterilization at 121deg C, 1.3 bar 20 minutes, or
- Steam sterilization at 270deg F, 41.84 psi, 4 minutes or
- Steam sterilization at 134deg C, 2.3 bar, 4 minutes

- Stand the hand grips vertically with the open side facing downwards.

- Do not exceed a sterilization temperature of 134deg C.

- The hand grips must be sterilized individually in packaging suitable for steam sterilization.

Note: The sterilization instructions are the same for the predicated devices, additional details can be found in each Operator Manual.

Electromagnetic Compatibility:

The TruLight 5520 and 5530, same as their predicated devices, comply with the requirements of the IEC 60601-1-2: 2007 "General requirements for safety-Collateral standard: electromagnetic compatibility-Requirements and tests"

Performance Data:

The TruLight 5520 and 5320 lighting systems have been tested to the same standards as the predicated devices and are found to have similar or improved performance features to the predicated devices.

The TruLight 5520 and 5320 lighting systems were reviewed with a thorough risk analysis by TRUMPF and additional third party experts to ensure the safety of our customers and their patients. TRUMPF Medizin Systeme GmbH + Co. KG. risk analysis reviewed possible mechanical, electronic, radiological, and handling failures associated to the TruLight and TruLight ALC+. Additional details are provided in tab G.

The device has been tested to IEC60825-1:2007 (2nd Edition). The laser compares to similar devices such as the Helion 501 and 701 lighting systems with Class 2 lasers.

These comparisons and test results have verified the new device is not any less safe or effective than the predicated devices.

Safe and Effective:

The TruLight 5520 and 5320 lighting systems have been tested to the same standards as the predicated devices. They have been subject to a thorough risk analysis. They have additionally been tested to IEC60825-1:2007 (2nd Edition). They compare to devices with Class 2 lasers similar to that of the ALC+, such as the Helion 501 and 701 lighting systems. These comparisons and test results have verified the new device is not any less safe or effective than the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TRUMPF Medizin Systeme GmbH + Co. KG
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle, North Carolina 27709

OCT 2 6 2010

Re: K102758
Trade/Device Name: TruLight 5520 and TruLight 5320
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY, FQP, FTD, FSQ
Dated: October 13, 2010
Received: October 14, 2010

Dear Mr. Rongero:

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

OCT 2 6 2010

510(k) Number (if known):

Device Name: Surgical Light, Ceiling Mounted, TruLight

Indications for Use: The TRUMPF Surgical lights are intended to locally illuminate an operating or examination area of the patient's body with high intensity 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)

Neil R. Ogden for mxm

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

510(k) Number K102758