K061317

JUN 22 2006

5. 510 (k) Summary

Submitter:	TRUMPF KREUZER Medizin Systeme GmbH + Co. KG Benzstraße 26 82178 Puchheim Germany
Contact Person:	Willibald Hiemer Manager Regulatory Affairs Phone: ++49 89 80 90 7 - 0 Fax: ++49 89 80 90 7 - 20
Preparation Date:	April 28, 2006
Trade Name:	iLED
Common Name:	Surgical lamp
Classification Name:	Light, Surgical, Ceiling Mounted
Device Description:	The iLED surgical light is suitable for all types of surgical procedures. The iLED light heads consists of several hexagonal modules, which contain the LEDs with their optical devices. Each LED with its optical device illuminates the complete light field. The iLED5 has one center module and four edge modules; the iLED3 has three edge modules for the illumination. Each light head has its own control to adjust the illumination parameters. The light intensity is adjustable between 30% and 100%, the color temperature between 3500 K and 5000 K. A dimming of the light to the point of an application at endoscopical working is possible and a adaptability to different situations (shadow control) to improve the illumination of the surgical field. With the use of LEDs as light sources, TRUMPF realizes a high illumination intensity with a low heat radiation and a durability of at least 4 times compared with gas-discharging lamps.

	The light incorporates easy-to-operate swivel arms and can be combined to systems with one, two or three light heads of the type iLED3 or iLED5. An optional CCD-video-camera is available and the light could be combined with TRUMPF KREUZER ceiling mounted support systems.
Intended Use of the Device:	The iLED lighting system is for illuminating an examination and surgical site on the patient in the clinic and doctor's office.
Indication for use:	The surgical light iLED is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow fee, "cold" light.
Predicate Device:	CHROMOPHARE X 65 K# 024132
Substantial Equivalence:	The iLED is substantially equivalent to the surgical light CHROMOPHARE X 65. Any difference that exists between the CHROMOPHARE X65 and the iLED has no negative effect on safety or effectiveness and actually enhances the usefulness in the chosen application.
Main Difference:	The light source **L**ight**E**mitting**D**iode, used by iLED, has a life time, which is 4 times the life time of a gas-discharge lamp. The CHROMOPHARE has two light sources whereas the iLED use 36 or 37 light sources per module. A failure of one light source of the iLED reduces the light intensity scarcely.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2006

Trumpf Kreuzer Medizin System GmbH
% Underwriters Laboratories, Inc.
Mr. Jeffrey D. Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K061317
Trade/Device Name: iLED
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulation Class: II
Product Code: FSY
Dated: June 30, 2006
Received: June 30, 2006

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indication for use Statement

510(k) Number: K061317

Device Name: iLED

Indications for use:

The surgical light iLED is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow fee, "cold" light.

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

(PLEASE DO NOT WIRTE BELOW THIS LINE – CONTINUE ONANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061317 PAGE 10 of 137 PAGES