510 (k) Summary

K080857

Submitter:	BERCHTOLD Holding GmbH Ludwigstaler Straße 125 D- 78532 Tuttlingen Germany
Contact Person:	Silke Goral Regulatory Affairs Phone: 0049 7461 181-155 Fax: 0049 7461 181-8155 Silke.Goral@BERCHTOLD.biz
Preparation Date:	January 16, 2008
Trade Name:	CHROMOPHARE® E 805 CHROMOPHARE® E 800 CHROMOPHARE® E 655 CHROMOPHARE® E 650 CHROMOPHARE® E 550 CHROMOPHARE® E 520
Common Name:	Surgical lamp
Classification Name:	Light, Surgical, Ceiling mounted
Predicate Device:	BERCHTOLD CHROMOPHARE® D650 (K965130) BERCHTOLD CHROMOPHARE® X65 (K024132)
Device Description:	The new BERCHTOLD CHROMOPHARE® E805, E800, E655, E650, E550, and E520 (collectively known and referred to in this document as CHROMOPHARE® Exxx) surgical lights are suitable for all types of surgical procedures. With the use of gas-discharging lamps or Halogen bulbs in these lights, BERCHTOLD realizes high illumination intensity with a lower heat radiation and less pattern variation compared to previous generations of BERCHTOLD products. The light features easy-to-operate swivel arms, auto switching to the secondary lamp in case of failure of the primary lamp, and an easy-to-exchange lamp cartridge. Each light functions with an optional integrated CCD video camera and/or with upward "EndoLite" for endoscopic procedures. The lights could be combined among each other.
Intended Use of the device:	The CHROMOPHARE® Exxx is intended to be used to provide visible illumination of the surgical field or the patient.
Indications for Use:	The surgical lights BERCHTOLD CHROMOPHARE® E805, E800, E 655, E 650, E 550 and E 520 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

APR 10 2008

Summary of technological characteristics compared to the predicate device

The BERCHTOLD CHROMOPHARE® Exxx is substantially equivalent to the surgical lights BERCHTOLD CHROMOPHARE® D 650 (K965139) and CHROMOPHARE® X 65 (K024132). Similarities and differences are tabulated below. Any differences between the CHROMOPHARE Exxx and the predicate devices do not alter the safety or efficacy of the device.

	Legally marketed device CHROMOPHARE® X65	New devices CHROMOPHARE® E805	CHROMOPHARE® E655
Intended use	Illumination of the operating site on a patient's body	same	same
Input power	120V, 1- phase lines, 60Hz	same	same
Protection against electrical shock	Class I	same	same
Diameter of light body	650mm	799mm	649mm
Diameter of polygon reflectors	580mm	680mm	520mm
Number of mirrored reflector elements	800	720	720
Lamp technology	Metal halide discharging	same	same
Polygon Reflector	Multi-piece	Single piece	Single piece
Power consumption of bulb	72W	150W	same
Light / heat filter technology incl. UV light filter mechanism	ThermoSorb®	same	same
Color rendering index R_a	94	same	same
Color temperature	4500°K	4300°K	4300°K
Central illuminance (at 1m)	80000 – 160000lux	same	same
Light field diameter	170 – 280mm	200 – 330mm	same
Depth of illumination	1250mm	1200mm	1300mm
Total irradiance E_e	550W/m²	560W/m²	560W/m²
UV- irradiance (≤400nm)	2.0W/m²	same	same
Light focusing mechanism	Rotating of Handle	same	same
Life time of bulb	5000h	same	same
Bulb life time indicator	Yes	same	same
Automatic switching to the reserve bulb	Yes	same	same
Bulb replacement indicator	Yes	same	same
Reusable steam sterilizable lamp handle	Yes	same	same
Additional light controls in separate wall box	Standard	same	same
EndoLite in the light head (ambient illumination for minimally invasive surgeries)	Optional feature	same	same
CCD video camera located in sterilizable lamp handle	Optional feature	same	same
Automatic regulation of intensity	No	AUTOlux	No

	Legally marketed device CHROMOPHARE® D650	New devices CHROMOPHARE® E800	CHROMOPHARE® E650	CHROMOPHARE® E550	CHROMOPHARE® E520
Intended use	Illumination of the operating site on a patient's body	same	same	same	Same
Input power	120V, 1- phase lines, 60Hz	same	same	same	Same
Protection against electrical shock	Class I	same	same	same	Same
Diameter of light body	650mm	799mm	649mm	579mm	579mm
Diameter of polygon reflectors	580mm	680mm	520mm	460mm	460mm

Number of mirrored reflector elements	800	720	720	720	720
Lamp technology	Halogen	same	same	same	Same
Polygon Reflector	Multi-piece	Single piece	Single Piece	Single piece	Single piece
Power consumption of bulb	150W	same	same	same	150W
Light / heat filter technology incl. UV light filter mechanism	ThermoSorb®	same	same	same	Same
Color rendering index R_a	94	93	93	93	93
Color temperature	4500°K	4300°K	4300°K	4300°K	4300°K
Central illuminance (at 1m)	70000 – 130000lux	80000 – 160000lux	80000 – 160000lux	65000 – 130000lux	80000lux
Light field diameter	150 – 280mm	200-300mm	170 – 280mm	150 – 250mm	200mm
Depth of illumination	1200mm	same	1300mm	1250mm	1250mm
Total irradiance E_e	485W/m²	560W/m²	507W/m²	455W/m²	280W/m²
UV- irradiance (≤400nm)	2.6W/m²	same	Same	same	Same
Light focusing mechanism	Rotating of handle	same	Same	same	No
Life time of bulb	1000h	same	Same	same	Same
Bulb life time indicator	No	same	Same	same	Same
Automatic switching to the reserve bulb	Yes	same	Same	same	Same
Bulb replacement indicator	Yes	same	Same	same	Same
Reusable steam sterilizable lamp handle	Yes	same	Same	same	Same
Additional light controls in separate wall box	Optional feature	Standard	Standard	Standard	No
EndoLite in the light head (ambient illumination for minimally invasive surgeries)	Optional feature	same	Same	same	No
CCD video camera located in sterilizable lamp handle	Optional feature	same	Same	same	No

Performance Summary: This device conforms to IEC 60601-2-41:2001 specifications for performance of surgical lamps. This device conforms to IEC 60601-1 and IEC 60601-1-2 for electrical safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2008

Berchtold Holding GmbH
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K080857
Trade/Device Name: CHROMOPHARE® E 805, CHROMOPHARE® E 800, CHROMOPHARE® E 655, CHROMOPHARE® E 650, CHROMOPHARE® E 550, CHROMOPHARE® E 520
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: March 25, 2008
Received: March 27, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K080857

Device Name:

CHROMOPHARE® E 805
CHROMOPHARE® E 800
CHROMOPHARE® E 655
CHROMOPHARE® E 650
CHROMOPHARE® E 550
CHROMOPHARE® E 520

Indications for Use:

The surgical lights BERCHTOLD CHROMOPHARE® E 805, E 800, E 655, E 650, E 550 and E 520 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080857