K120392 1of2

FEB 16 2012

510 (k) Summary

Submitter:	BERCHTOLD Holding GmbH Ludwigstaler Straße 125 D- 78532 Tuttlingen Germany
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Preparation Date:	November 18, 2011
Trade Name:	CHROMOPHARE® F 628 CHROMOPHARE® F 528
Common Name:	Surgical lamp
Classification Name:	Light, Surgical, Ceiling mounted
Predicate Device:	BERCHTOLD CHROMOPHARE® E 668 (K090378)
Device Description:	The new BERCHTOLD CHROMOPHARE® F 628 and F 528 surgical lights are suitable for all types of surgical procedures. With the use of Light Emitting Diodes (LEDs) in combination with reflector technology, 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. Each light functions with an optional integrated in-light video camera and/or with upward "EndoLite" and/or with downward "GuideLite" for endoscopic procedures. The lights could be combined among each other or with other CHROMOPHARE devices, on ceiling mounted, wall mounted and floorstand configurations.
Intended Use of the device:	The CHROMOPHARE® F 628 and F 528 are intended to be used to provide visible illumination to the surgical field of the patient.
Indications for Use:	The surgical lights BERCHTOLD CHROMOPHARE® F 628 and F 528 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Technological Characteristics Comparison Summary:

The BERCHTOLD CHROMOPHARE® F 628 and F 528 have the same technological characteristics as the predicate BERCHTOLD CHROMOPHARE® E 668 (K090378). Following is a summary of the technological characteristics of the new device in comparison to those of the predicate device: The input power is the same; the protection against electrical shock is the same; the lamp technology is the same, the power consumption per sources is comparable; the color rendering index is slightly higher, the color temperature is the same, the focusing mechanism is the same; the use of sterilizable and disposable handles is the same; the control system via wall boxes is the same; and ambient illumination and in-light camera system capabilities are the same. The predicate device and the new F 628 and F 528 utilize differing materials in construction, such as a composite frame for the new device versus an all-aluminum housing for the predicate device. Both devices were subjected to testing in accordance with IEC 60601-1 and IEC 60601-1-2 for mechanical and electrical safety, just as the predicate device. Any technological differences between the F 628 and F 528, and the predicate device do not affect the safety and efficacy, or alter the intended use.

Performance Comparison Summary:

This device conforms to IEC 60601-2-41:2001 specifications for performance of surgical lamps. Testing was conducted in accordance with this standard to support substantial equivalence. The F 628 and F 528 meet, as did the predicate device, all requirements of the performance standard and achieved specified desired values per the product design specifications. Clinical testing was not required or utilized to support substantial equivalence.

Substantial Equivalence Conclusion and Determination:

Based on the summarized technological characteristic similarities and differences, in conjunction with the testing conducted to support conformity to IEC 60601-2-41:2001 and performance data tabulated in detail within this submission per FDA "Guidance Document for Surgical Lamp 510(k)s", the CHROMOPHARE F 628 and F 528 are found to be substantially equivalent to the identified predicate device.

Conformity 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 medical device and electrical safety.

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

FEB 16 2012

Berchtold GmbH and Co. KG
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K120392
Trade/Device Name: Chromophare® F 628
Chromophare® F 628
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: February 06, 2012
Received: February 08, 2012

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,

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

510(k) Number (if known):

Device Name:

CHROMOPHARE® F 628
CHROMOPHARE® F 528

Indications for Use:

The surgical lights BERCHTOLD CHROMOPHARE® F 628 and F 528 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)

Neil R. Ogden for MXR

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

510(k) Number K120392