K024132

510(k) Summary

MAR 21 2003

Submitter:	BERCHTOLD Holding GmbH Ludwigstaler Str. 25 D-78532 Tuttlingen Germany
Contact Person:	Jörg Schneider Regulatory Affairs Phone: 0049 7461 181155 Fax: 0049 7461 181100 joerg.schneider@berchtold.de
Preparation Date:	December 02, 2002
Trade Name:	CHROMOPHARE® X 65
Common Name:	Surgical lamp
Classification Name:	Light, Surgical, Ceiling Mounted
Device Description:	The new BERCHTOLD CHROMOPHARE® X 65 surgical light is suitable for all types of surgical procedures. With the use of gas-discharging lamps in the new light BERCHTOLD realizes a higher illumination intensity with a lower heat radiation. The light incorporates easy-to-operate swivel arms auto switching on the second lamp in case of failure of the main lamp and an easy-to-exchange lamp cartridge. Also an optional CCD-video-camera is available and a special version with "EndoLite" for endoscopical working. The light could be combined with other BERCHTOLD lights.
Intended Use of the Device:	The CHROMOPHARE® X 65 is intended to be used to provide used to provide visible illumination of the surgical field or the patient.
Substantial Equivalence:	The BERCHTOLD CHROMOPHARE® X65 is substantially equivalent to the surgical light BERCHTOLD CHROMOPHARE® D650 (K965130). Any difference that exists between the CHROMOPHARE® D650 and the X 65 has no negative effect on safety or efficacy and actually enhances the usefulness in the chosen application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Mr. Jörg Schneider
Regulatory Affairs
Berchtold Holding GmbH
Ludwigstaler Str. 25
Tuttlingen, Germay D-78532

Re: K024132
Trade/Device Name: CHROMOPHARE® X65
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: February 13, 2003
Received: February 19, 2003

Dear Mr. Schneider:

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.

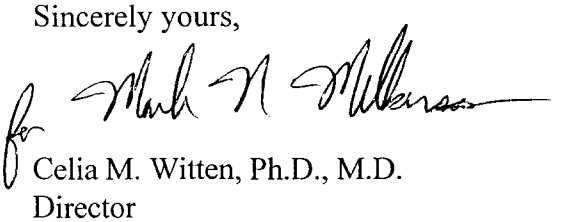
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K024132

INDICATION FOR USE

The surgical light BERCHTOLD CHROMOPHARE® X65

is intended to illuminate locally the operating site on the patient's body

with a high intensity, shadow free, "cold" light.

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

510(k) Number K024132