

K 974433**K. 510(k) SUMMARY (As Required By 21 CFR 807.3):**

FEB 20 1998

FÜNFUNDSTIEBZIG JAHRE

Date: November 20, 1997

Submitter:

Berchtold GmbH & Co
Ludwigstaler Str. 25
D-78532 Tuttlingen
Germany

Phone number: 0049 7461 181-0
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Contact person: Wolfram K. Hill
Manager R & D

Device Name:

Trade Name: CHROMOPHARE® D 500
CHROMOPHARE® D 530

Classification name: Light, Surgical, Ceiling Mounted

Device Description:

The new Berchtold CHROMOPHARE® D 500 and D 530 surgical lights are suitable for all types of surgical procedures and offer the physician a natural (whiter) and "colder" light. The light quality is based on a optical double filter technique.

The CHROMOPHARE® D 530 provides a light intensity of up to 110000 lux and the CHROMOPHARE® D 500 up to 85000 lux.

The lights have features like 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. For the CHROMOPHARE® D 530 there is also an optional CCD-video camera available and a special version with „EndoLite“ for endoscopical procedures. The lights could be combined with other Berchtold lights. The lights have been designed to and meet the requirements of the IEC 601 and UL 2601 regulation for safety.

Intended Use:

The surgical lights, CHROMOPHARE® D 500 and D 530, are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Substantial Equivalence:

The CHROMOPHARE® D 500 and D 530 surgical lights are substantially equivalent to the surgical light CHROMOPHARE® D 650 which is approved by FDA under K965130.

Any difference that exists between the CHROMOPHARE® D 500/530 and the CHROMOPHARE® D 650 has no negative effect on safety or efficacy and actually enhances the usefulness in the chosen application. Safety of the lights, as indicated above, has been established by meeting the requirements of IEC 601 and UL 2601.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1998

Mr. Wolfram K. Hill
Manager R & D
Berchtold GmbH & Company
Ludwigstaler Street 25
D-78532 Tuttlingen
Germany

Re: K974433
Trade Name: CHROMOPHARE® D 500 and D 530 Surgical Lights
Regulatory Class: II
Product Code: FSY
Dated: November 21, 1997
Received: November 24, 1997

Dear Mr. Hill:

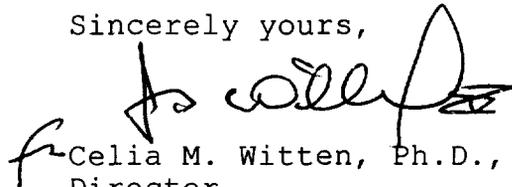
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

Enclosure



M. INDICATION FOR USE:

The surgical lights, CHROMOPHARE® D 500 and D 530, are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Wolfram Hill

Wolfram Hill

Nov. 24, 98

Date

Prescription Use
(Per 21 CFR 801.109)

X

[Signature]

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

2974433