JUL 20 1999

BERCHTOLD

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

K990656

Date: June 7, 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 530 LDR

Classification name: Light, Surgical, Ceiling Mounted

Device Description:

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

The CHROMOPHARE® D 530 LDR provides a light intensity of up to 85000 lux.

The light has features like a suspension mechanism which will allow to move the light head motordriven up and down, auto-switching on the second lamp in case of failure of the main lamp and an easy to exchange lamp cartridge. The new suspension allows the surgeon to move the light out of the treatment area, which is of interest e.g. in labor and delivery rooms. The light has been designed to and meets the requirements of the IEC 601 and UL 544 regulation for safety.

Intended Use:

The surgical light, CHROMOPHARE® D 530 LDR is 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 530 LDR surgical light is substantially equivalent to the surgical light CHROMOPHARE® D 500 which is approved by FDA under K974433.

Any difference that exists between the CHROMOPHARE® D 530 LDR and the CHROMOPHARE® D 500 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 544.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Mr. Wolfram K. Hill
Manager, Research and Development
Berchtold GmbH & Co.
Ludwigstaler Str. 25
Postfach 4052
D-78505 Tuttlingen,
Germany

Re: K990656
Trade Name: CHROMOPHARE® D 530 LDR
Regulatory Class: II
Product Code: FSY
Dated: June 7, 1999
Received: June 11, 1999

Dear Mr. Hill:

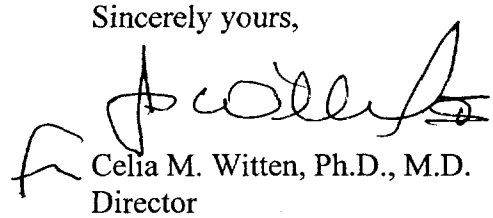
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (Premarket Approval), 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 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 device 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 device as described in your 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 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 device, 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,



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

BERCHTOLD

M. INDICATION FOR USE:

The surgical light, CHROMOPHARE® D 530 LDR, is intended to illuminate locally the operating site on the patient´s body with a high intensity, shadow free, "cold" light.

Wolfram Hill

Wolfram Hill

June 7, 99

Date

990656

510(k) Number

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990657

Prescription Use X
(Per 21 CFR 801.109)