MAY 27 1999 K991527

BERCHTOLD

8.0 510(k) SUMMARY

As Required By 21 CFR 807.92

Submitter:

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

Phone number: 0049 7461 181-0
Fax number: 0049 7461 181-100

Contact person: Wolfram K. Hill
Manager R & D

Device Name:

Trade Name: CHROMOPHARE® D500
CHROMOPHARE® D530
CHROMOPHARE® D650

Classification name: Light, Surgical, Ceiling Mounted
Product code: FSY
Device class: Class II

Device Description:

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

The CHROMOPHARE® D Series lights provides a light intensity from 85000lx up to 150000 lux.

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. For the CHROMOPHARE® D650 and D530 is also an optional CCD-video camera available and a special version with „EndoLite" for endoscopical working. The light could be combined with other Berchtold lights and the Hermes OR Control Center of Computer Motion, Inc.. The light has been designed to and meets the requirements of the IEC 601 and UL 544 regulation for safety.

Intended Use:

The intent of the CHROMOPHARE® D650 is to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light. Light functions could be controlled by touch panel mounted at the wall box. The connection to the HERMES OR Control Center provide the surgeon with the option of using voice-activated control of the settings and adjustments of the CHROMOPHARE® D650. This is to allow for simplified and more direct control of the Light settings by the physician, thereby eliminating the necessity of relying upon verbal communications between the surgeon and other personnel in the operation room in order to adjust the Surgical Light.

Substantial Equivalence:

The CHROMOPHARE® D650 described in this submission is substantially equivalent to the CHROMOPHARE® D659 described in K965130. Any difference that exists has no negative effect on safety or efficacy and actually enhances the usefulness in the chosen application. Safety of the medical supply units, 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

MAY 27 1999

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

Re: K991527
Trade Name: Chromophare D500, D530, D650
Regulatory Class: II
Product Code: FSY
Dated: April 28, 1999
Received: May 3, 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,

for 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

4.0 Indication for Use

The Surgical lights CHROMOPHARE® D500, D530 and D650, are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Wolfram Hill
Manager R&D
Berchtold GmbH & Co.

May 19, 99
Date

K 991527
510(k) Number

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991527