

Summary

K 973466

Date: 04. August 1997

Address: HERAEUS MED GmbH  
Heraeusstraße 12 - 14  
63450 Hanau

Contact person: Mark Schulz

Establishment Registration Number: 8010602

Proprietary Name: HANAULUX *blue 75* and  
HANAULUX *blue 120*

Common Name: Examination Luminaire and  
Surgical Luminaire

Device Classification: Regulatory Class II, 79FSY

Compliance with Standards: UL 2601 Safety of Medical Electrical  
Equipment  
IEC 601-1 Safety of Medical Electrical  
Equipment  
IEC 601-2-41 Safety of Surgical  
Luminaires and Luminaires for Diagnosis  
UL 153 Portable Electric Lamps

Substantial equivalence: This product is similar in funktion to the  
existing surgical lighting program HANAULUX "City" series, HANAULUX 2000 and  
HANAULUX *blue 30 / 80*.

OCT 24 1997

Description of Device:

Hanaulux *blue* 75 / 120 is an Examination and Surgical Light with two lighthouse combinations of *blue* 75 and *blue* 120. The Hanaulux<sup>(R)</sup> *blue* 75 / 120 is principally the same as the Hanaulux<sup>(R)</sup> *blue* 30 / 80 in design, material and function. They are intended for illumination purpose and are not intended for therapeutic use and direct contact with the patient.

All used plastics are molded of UL Recognized Component material.

All internal wiring is either Listed fixture wire or Recognized Component appliance wiring material.

The maximum of UV Irradiance is lower than  $6 \text{ W} / \text{m}^2$ .

Hanaulux<sup>(R)</sup> *blue* 80 Hospital is intended to be installed in accordance with the National Electrical Code. The system is intended to be connected to a remote, listed, isolating type, 24V transformer.

August 04, 1997

Mark Schulz

Development Engineer  
Electric Construction

**Heraeus**  
MED  
GmbH  
Postfach 15 64  
D-63405 Hanau



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Mark Schulz  
Heraeus Med GmbH, Hanau  
Heraeusstrasse 12-14  
63450 Hanau  
Germany

OCT 24 1997

Re: K973466  
Trade Name: *Hanaulux® blue 75 and Hanaulux® blue 120*  
Regulatory Class: II  
Product Code: FSY  
Dated: August 8, 1997  
Received: August 15, 1997

Dear Mr. Schulz:

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.

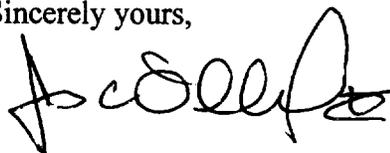
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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 submissions 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.

Page 2 - Mr. Mark Schulz

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 devices 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,

  
f 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

510(k) Number (if known): K 973466

Device Name: HANAULUX blue 75 / 120

Indications For Use:

**Intended Use:**

Hanaulux blue 75 / 120 are surgical luminaires used in the patient area and intended to illuminate locally the body of the patient. They are installed as a system of one, two or three luminaires and are intended to support the treatment and diagnosis. They are intended to be used in operating rooms and not for direct contact with patient.

Heraeus Med GmbH

M. Schulz



**Heraeus**

**MED  
GmbH**

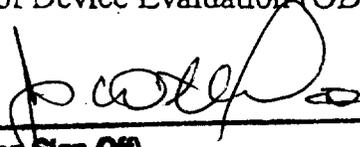
Postfach 15 64

D-63405 Hanau

Regulatory Affairs Manager

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number \_\_\_\_\_

K973466

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)