Summary Report with respect to the Guidance Document (Section 12)

The guidance document with the standard mentioned in the guidance for Surgical Lamps were taken into consideration to evaluate and to reduced the risk of the surgical light. Most of the technological solution to avoid any risk associated with the device are given in the IEC 60601-1 and IEC 60601-2-41 standard.

The protection of the user and the patient regarding electrical hazards were covered by the generic standard IEC 60601-1. The device were tested with respect to the standard and passed all requirements.

The particular standard IEC 60601-2-41 that is also required to be fulfilled by FDA`s guidance document for surgical lamps covers among other things the following aspects:

1.) specific additional electrical requirements for surgical lamps
2.) additional requirements about the accuracy of operation data
3.) additional requirements for the illumination of infrared and ultra violet emission
4.) additional requirements for the mechanical strength
5.) additional requirements for the labeling to exactly define the intended use of the lamp

These specific requirements covers the hazards of the surgical lamps and are specific for those devices. If these requirements are fulfilled the potential hazard will be avoided. The Sola series were tested with respect to the standard IEC 60601-2-41 and fulfil the requirements.

Other criteria of the guidance document that covers supplemental requirements like e.g. biocompatibility and software issues were not taken into consideration because they do not apply for the Dräger Sola series.

Nevertheless, we evaluated the probability of risks for surgical lights and their estimations. Please find attached the evaluation of the potential hazard. These hazards have already been eliminate by carrying out the development due to the solution given in the evaluation.

Dec. 1998

Frank Clanzett, Regulatory Affairs

Evaluation of potential hazards (with respect to En 1441)

- **Risk Propability**

Potential danger	Probability	Estimation of risks
Electricity	A	-According to IEC 60601-1 and IEC 60601-2-41 - Based on many years of experience in manufacturing lights during which no complaints have been registered, there is no danger to the user or patient from electrical energy
Mechanical Strength	A	- The stated carrying capacity and torque are calculated with a safety factor of 4x. (Also requirements in IEC 60601-2-41.
Movable parts	A	- Feather arm. The vertical adjustment optimally compensates for the weight of the light head. Further adjustment can be made as described in the User's Manual
Movable parts	A	- The light head maintains the position in which it is placed. The moveable parts are held in place with the help of mechanical or electromechanical brakes. - Conformity to IEC 60601-2-41
Suspended loads	A	- Detachment of the light head from the feather arm. Not possible when properly installed. - The loads are calculated with a safety factor of 4x. - Parts held in place by screws are protected against detachment by specific safety mechanisms
Insufficient energy	B	- In case of interruption of the main power supply or a large voltage reduction, a relay will initiate a switchover to the emergency power supply provided by the user.
Bulb explosion	A	- Seldom occurs. The fully enclosed light system eliminates any potential danger from glass splinters
Diffusing lens	A	- When properly used, the diffuser lens cannot be broken. Manufacturing standards and in-house inspection of each lens nearly eliminate all residual risks. (Also IEC 60601-1)

A: unlikely
B: could occur if a defect is present
C: could occur if several defects are present

- **Assessment of the riks**

  This product, inclusive of the previous product MLxx0, has been on the market in Europe for 4 years. It satisfies the demands of the user. No complaints have been received which have necessitated a change in the product.

  The development has generally followed the fundamentals of the accepted standards and is also based on the experience and findings of the previous product generation.

- **Evaluation of the product`s safety**

  The data supports the assertion that the risks are negligible when device is used in accordance with its intended use.

Note: This document is a translated version of the original German document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 1999

Mr. Frank Clanzett
Regulatory Affairs
Drager Medizintechnik GMBH
53/55 Moislinger Allee
23542 Luebeck
Germany

Re: K984611
Trade Name: Sola Surgical Lights
Regulatory Class: II
Product Code: FSY
Dated: December 23, 1998
Received: December 29, 1998

Dear Mr. Clanzett:

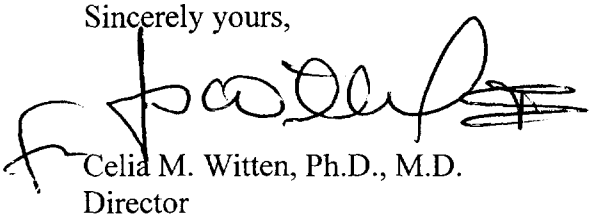
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Appendix 2

Indications for Use Form

510(k) Number (if known): K984611

Device Name: Sola Surgical Lights

Indications for Use:

The Dräger Sola surgical lights (Sola 1000, 700, 500) are intended to locally illuminate an operating or examination area of the patient's body with high intensity light.

The Dräger Sola 300 is intended to be used as an examination light or as a satellite light within a surgical lighting system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984611