K053364

FEB 2 3 2006

EXHIBIT 2
510(k) Summary
Waldmann Lighting
9 W. Century Drive
Wheeling, IL 60090
Phone: 847-520-1060
Fax: 847-520-1730
Contact: Les Kaminski, Plant Manager
Prepared November 5, 2005

1. **Identification of the Device:**
   Proprietary-Trade Name: Halux® Iris Examination and Surgical Lamp
   Classification Name: lamp, surgical Codes FTD and FSY..
   Common/Usual Name: Surgical lamp

2. **Equivalent legally marketed devices** Burton Medical Products Corp Outpatient® Minor Surgical Light, K042395

3. **Indications for Use (intended use)** Halux® Iris is designed to provide the required illumination for surgeries, procedures, and examinations of patients. The Halux® Iris Examination and Surgical Lamp is to be used with various mounting configurations in operating rooms, examination rooms, emergency rooms and all other health care facilities where the need for additional illumination exists.

4. **Description of the Device:** Whether in the doctor's office, examination rooms, emergency facilities, intensive care clinics, pre- or post-operative rooms, the Iris provides high intensity light where it is needed. The Iris is user friendly. With its high quality illumination, the halux® Iris is perfect for lighting all kinds of examinations and treatments. Outstanding features of this luminaire include the unique shape of the lamp housing, the combination facetted and parabolic technology of its reflector, and its smooth operating and spring-loaded articulating arm. Highlights of our examination lamp:
   Smooth Operation and adjustability
   Precise positioning
   Compact and enclosed articulation system with counterbalance system.
   A specially designed reflector system insures a precise light source that renders true colors.
   The Iris is available in ceiling, wall and floor versions.
   halux® Iris is a medical product manufactured in accordance with EG 93/42 Class 1 and is constructed in accordance with EN 60 601-2-41 (UL2601).

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and laboratory testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Technical Specifications		
Items	Value	
Manufacturer	Burton Medical	Waldmann Lighting
Model number(s)	Outpatient Plus or CoolSpot	Halux® Iris
K number	K042395	
Electrical requirements	120 V. 50-60 Hz	SAME
Light Output	4800 footcandles	45000 lux at 0.8 m (4180 footcandles)
Color temperature	3600 K	4000 K
Wattage	150 watts (three 50 watt halogen)	One 50 watt Halogen
Power source	Transformer	SAME
Operating environment	Minor surgeries	SAME
Bulb operating life	2000 hrs.	Up to 4000 hrs.
Case material	Steel and plastics	SAME
Warranty	3 years	2 years
Safety listing	UL	UL

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Waldmann Lighting that the Halux® Iris Examination and Surgical Lamp is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2006

Waldmann Lighting
c/o Mr. Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield, Illinois 60015

Re: K053364
Trade/Device Name: Halux® Iris Examination and Surgical Lamp
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTD
Dated: February 13, 2006
Received: February 17, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053364

Device Name: Halux® Iris Examination and Surgical Lamp

Indication for use: Halux® Iris is designed to provide the required illumination for surgeries, procedures, and examinations of patients. The Halux® Iris Examination and Surgical Lamp is to be used with various mounting configurations in operating rooms, examination rooms, emergency rooms and all other health care facilities where the need for additional illumination exists.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of General, Restorative, and Neurological Devices

510(k) Number K053364