K101537

510(k) Summary

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Submitter:	Scot D. Kinghorn Quality Assurance Regulatory Affairs Manager Burton Medical Products Corporation 21100 Lassen Street Chatsworth, CA 91311
Contact Person:	Scot D. Kinghorn Quality Assurance Regulatory Affairs Manager Burton Medical Products Corporation 21100 Lassen Street Chatsworth, CA 91311 Phone: 800-444-9909 x 181 email: skinghorn@burtonmedical.com
Date prepared:	28-May-10
Trade/Device name:	AIM 200® OR Major Surgical Light
Regulation number:	21CFR 878.4580
Regulation name:	Surgical Lamp
Regulatory Class:	Class II
Product Code:	FSY
Predicate Device:	Outpatient®III, Minor Surgical Light (Note: the name of this device was changed to "AIM 100® Minor Surgery Light" subsequent to clearance by the FDA.)
Predicate "K" number:	K042395
Predicate submitter:	Burton Medical Products Inc.
Predicate clearance date:	01-Dec-2004
Product description:	"Description and Application: · The new AIM 200® OR is intended to be used in Acute care arena in operating theaters, emergency rooms, trauma centers, and endo-suites as well as in ASC's for endo-suites, plastic surgery, ophthalmology and orthopedic procedures. It is available in floor, wall, single ceiling and double ceiling models. · The new AIM 200® OR combines the smart and versatile styling of the existing AIM 50® and AIM 100® with the increased luminance of a Major OR product. · The AIM 200® OR uses proven AIM 100® optical modules at increased

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powers to yield illuminance of 90,000 Lux at 1 meter while meeting the D50/D10 light distribution ratio required by the IEC 60601-2-41 standard for Major Surgical Lighting. · Supported by an industry leading 5 year warranty, the AIM 200® OR is yet another Burton product that exceeds our customers' demands" Source: *Burton AIM Family Expansion Launch Manual.*

Intended Use:

The AIM 200® OR Major Surgical Light is designed to provide the required illumination for surgeries, procedures, and examinations of patients. · The AIM 200® OR Major Surgical Light 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.

Difference from Predicate Device:

The Indications For Use submitted with the predicate device (Outpatient®III, Minor Surgical Light aka AIM 100® Minor Surgery Light) indicated applications for **Minor** Surgery. The product for this submission (AIM 200® OR Major Surgical Light) has modified this application to include **Major** Surgery. It should be noted that AIM 100® and the AIM 200® OR are identical by composition. An alternate wiring from the transformer employed in the AIM 200® OR provides additional voltage at the light bulbs resulting in greater illumination than present in the AIM 100® configuration.

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Comparison Table:

Comparison Table	Predicate device	Submission device
Device name	Outpatient®III, Minor Surgical Light (AIM 100® Minor Surgery Light)	AIM 200® OR Major Surgical Light
Indications For Use	The Outpatient®III, Minor Surgical Light is designed to provide the required illumination for surgeries, procedures, and examinations of patients. Outpatient®III, Minor Surgical Light 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.	The AIM 200® OR Major Surgical Light is designed to provide the required illumination for surgeries, procedures, and examinations of patients. The AIM 200® OR Major Surgical Light 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.
Illuminance	63,000 Lux at 1 meter	90,000 Lux at 1 meter
Color Temperature	3500 K	3700 K
Diameter of Lighthead	51 cm (20 inches)	51 cm (20 inches)
Light Field Diameter	25 – 30 cm (10 – 12 inches)	25 – 30 cm (10 – 12 inches)
Depth of illumination	119 cm (47 inches)	119 cm (47 inches)
Focusing	Adjustable by rotating center handle	Adjustable by rotating center handle
Number of bulbs	3	3
Light Sources (Halogen)	35 W IRC, 12 volt, bi-pin	35 W IRC, 12 volt, bi-pin
Rated life of Halogen Lamp	2,000 hours	1,400 hours
Swivel Radius of Lam Housing – Ceiling Mounted	160 cm (63 inches) max.	160 cm (63 inches) max.
Height Movement of Lamp Housing – Ceiling Mounted	104 cm (41 inches) vertical movement	104 cm (41 inches) vertical movement
Power	116 Watts	105 Watts
Certifications	IEC/UL 60601 / IEC 60601-1-2 / IEC 60601-2-41 / MDD 93/42/EEC / CAN/CSA C22.2 601-1 M90	IEC/UL 60601 / IEC 60601-1-2 / IEC 60601-2-41 / MDD 93/42/EEC / CAN/CSA C22.2 601-1 M90
Mounting options	Single Ceiling, Double Ceiling, Floor, Wall	Single Ceiling, Double Ceiling, Floor, Wall
Warranty	5 year limited warranty	5 year limited warranty
Origin	Manufactured in the USA	Manufactured in the USA

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Performance Data:

The AIM 100® and the AIM 200® OR were tested (together) to the following standards:

- Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety UL 60601 – 1, Issued 2003-04-25 Ed.:1 Rev:2006/04/26
- Medical Electrical Equipment – Part 1: General Requirements for Safety General Instruction No 1; Supplement 1; 1994; CSA C22.2#601.1, Issue 1990/0101, Amendment 2 – February 1998, Update No. 2 (R2001)
- Medical Electrical Equipment – Part 2-41: Particular Requirements for the Basic Safety and Essential Performance of Surgical Luminaries and Luminaries for Diagnosis, IEC 60601-2-41:2000 Ed:1

A copy of the reports for this testing is included in tab 13 of this submission. This testing was initiated by Underwriters Laboratory and completed by Intertek.

Conclusion:

The products meet all requirements as defined in the above Safety and Performance standards and were issued an "Authorization to Mark" by Intertek. A copy of this document can also be found in tab 12 Performance testing. The AIM 200® OR performed as well as, or better than, the legally marketed predicate device, the AIM 100™ (aka Outpatient®III). The AIM 200® OR Major Surgery Light is thereby deemed to be safe and effective for it's intended use.

Substantial Equivalence:

The AIM 200® OR Major Surgical Light is substantially equivalent to the legally marketed predicate device, the AIM 100™ Minor Surgery Light (aka Outpatient®III).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 30 2010

Burton Medical Products Corporation
% Mr. Scot D. Kinghorn
Quality Assurance Regulatory Affairs Manager
21100 Lassen Street
Chatsworth, California 91311

Re: K101537
Trade/Device Name: AIM 200® OR Major Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: September 17, 2010
Received: September 24, 2010

Dear Mr. Kinghorn:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K101537

Device Name: AIM 200® OR Major Surgical Light

Indications for Use:

The AIM 200® OR Major Surgical Light is designed to provide the required illumination for surgeries, procedures, and examinations of patients. The AIM 200® OR Major Surgical Light 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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