INTEGRA
LIMIT UNCERTAINTY

589 Davies Drive
York, Pa 17402
Phone (717) 940-8335
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www. Integralife.com

510(k) Summary

K110528

MAY 1 1 2011

Submitted by:	Integra Burlington MA, Inc. 22 Terry Avenue, Burlington, MA 01803 USA
Contact Person:	Stephanie Sheesley, Regulatory Affairs Manager Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA Phone: (717) 717-840-2774 Fax: (717) 840-3509
Date Prepared:	February 16, 2011
Device Trade Name:	Integra™ LED Headlight System
Device Common Name:	Surgical Headlight
Classification Name:	Light, Headband, Surgical
Device Class:	Class II
Product Code:	FSR
CFR Classification:	21 CFR 886.4335
Predicate Device:	510(k) #K031548 Welch Allyn's Solid State Procedure Headlight

Device Description:
The Integra™ LED Surgical Headlight System is a self-contained headlight system that can be operated using either battery or direct power supply. Using a battery pack gives the surgeon complete portability allowing unrestricted movement in and around the operating suite. The direct power supply option can be used as a primary power source for unlimited operating time, or as a back-up to the battery system.

The Integra™ LED Surgical Headlight System utilizes an LED light source with an active cooling system. A thermostatically-controlled cooling fan draws air at a very low flow rate through ports on the side and back of the headlight module, quietly cooling the LED. The air is drawn through a system of ducts and is gently exhausted behind the surgeon.

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Indications For Use:
The Integra™ LED Surgical Headlight System is designed to provide illumination to aid visualization during minor surgical, diagnostic, or therapeutic procedures.

Predicate Device:

510(k) #	Device	Manufacturer
K031548	Solid State Procedure Headlight	Welch Allyn Inc.

Performance Standards:
No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Integra™ LED Surgical Headlight conforms to the following standards:

- CAN/CSA-C22.2 No. 601.1-M90 - "Medical Electrical Equipment Part 1: General Requirements for Safety"
- EN 60601-1: 1990 + A1: 1992 + A2: 1995 - "Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1: 1988 + A1: 1991 + A2: 1995 - "Medical Electrical Equipment Part 1: General Requirements for Safety"
- UL 60601-1, First Edition, 2003 - "Medical Electrical Equipment Part 1: General Requirements for Safety"
- IEC 60601-1- 8: 2003 (First Edition) in conjunction with IEC 60601-1 (1988) including Amendments 1 (1991) and 2 (1995).
- CAN/CSA E60335-1/4E, Fourth Edition, 2003 – "Household and Similar Electrical Appliances Safety Part 1: General Requirements"
- UL 60335-1, Fourth Edition, 2004 – "UL Standard for Safety of Household and Similar Electrical Appliances, Part 1:General Requirements"
- IEC 60335-2-29:2002 (Fourth Edition) + A1:2004 + A2:2009 in conjunction with IEC 60335-1:2001 (Fourth Edition) incl. Corrigendum 1:2002 + A1:2004 + A2:2006 incl. Corrigendum 1:2006

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Technological Characteristics:

Feature	Integra LED Surgical Headlight	Welch Allyn Solid State Headlight
LED Light Source	YES	YES
AC/DC Powered	YES	YES
Battery Powered	YES	YES
User Control of Attenuated Light Level	YES	NO
Fan Monitoring and Control	YES	NO
Over Temperature Monitoring and Control	YES	NO
Adjustable Light Positioning	YES	YES
Adjustable Illuminated Spot Size	YES	YES

Substantial Equivalence:

The Integra™ LED Surgical Headlight is substantially equivalent to the legally marketed predicate device based on performance testing. The Integra™ LED Surgical Headlight System has the same intended use, technological characteristics, and general operation as the predicate device identified. Minor differences between these devices simply improve performance and operating characteristics of the device and do not raise any new questions in regards to the system's safety or effectiveness.

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

MAY 1 1 2011

Integra Life Sciences Corporation
% Integra York PA, Inc.
Ms. Stephanie Sheesley
Regulatory Affairs Manager
589 Davies Drive
York, Pennsylvania 17402

Re: K110528
Trade/Device Name: Integra™ LED Headlight System
Regulation Number: 21 CFR 886.4335
Regulation Name: Operating headlamp
Regulatory Class: Class II
Product Code: FSR
Dated: February 23, 2011
Received: February 24, 2011

Dear Ms. Sheesley:

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 Peter D. Pfendler, D.D.S.

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

510(k) Number (if known): K110528

Device Name: Integra™ LED Surgical Headlight System

Indications for Use:

The Integra™ LED Surgical Headlight System is designed to provide illumination to aid visualization during minor surgical, diagnostic, or therapeutic procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

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

510(k) Number K110528