AUG 1 1 2003

K031548

"Abbreviated 510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, New York 13153 - 0220

Contact Person & Telephone: David Klementowski
(315) 685-4133

Date Summary Prepared: Monday, May 12th, 2003

Device Name: Classification Name – Headlamp, Operating, AC-Powered
Common/Usual Name – Solid State Procedure Headlight
Proprietary Name – LED Headlight

Predicate Device: 49003, Halogen Headlight manufactured by Welch Allyn, Inc., Skaneateles Falls, New York.

Device Description, intended Use & Effectiveness:

This product features an articulated projector that is mounted to a comfortable adjustable headband. The range of adjustability accommodates the majority of users. The actual source for the illumination is a high intensity white LED. The Solid State Procedure Headlight is indicated for providing illumination to aid visualization during minor surgical, diagnostic, or therapeutic procedures.

Technological Characteristics:

See attachment "III" for a comparison of the Solid State Procedure Headlight System to the predicate device.

Summary of Safety:

The system will be certified to the following general safety standards:

IEC60601-1	Medical Electrical Equipment, Part 1: General requirements for Safety, Amendment 1, and Amendment 2
IEC60601-1-2	Medical Electrical Equipment, Part 1: General requirements for safety 2: Electromagnetic Compatibility - Requirements and tests
IEC60825-1	Safety of laser products, Part 1: Equipment classification, requirements and user's guide

Summary of Effectiveness:

Completed design reviews and testing ensures that the Solid State Procedure Headlight System performs within the environment(s) for which is to be marketed. The safety testing complies with the indicated standards. Based on these results, and above referenced testing it is our determination that the device is safe, effective and performs within its design parameters as well as the legally marketed predicate device. Welch Allyn, Inc. will not market this device if it does not completely meet its design intent and safety functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2003

Mr. David Klementowski
Senior Manager Regulatory Affairs
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, New York 13153

Re: K031548
Trade/Device Name: Solid State Procedure Headlight
Regulation Number: 21 CFR 886.4335
Regulation Name: Light, Headband, Surgical
Regulatory Class: II
Product Code: FSR
Dated: May 12, 2003
Received: May 20, 2003

Dear Mr. Klementowski:

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031548

Device Name: Solid State Procedure Headlight

Indications For Use:

The Solid State Procedure Headlight is indicated for providing illumination to aid visualization during minor surgical, diagnostic, or therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

(Optional Format 1-2-96)

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

510(k) Number K031548