K971750

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

JUN 30 1997

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, N.Y. 13153-0220

Contact Person & Telephone: Colin Wolff
(315) 685-2525

Date Summary Prepared: May 2, 1997

Device Name: Classification Name - Surgical Lamp
Common/Usual Name - Illuminating Infusion Sleeve
Proprietary Name - Welch Allyn Phaco Illuminator

Predicate Device: Accessory Illuminating Infusion Sleeve by Michael Reynard, M.D. (ref. 510(k) #K964018)

Device Description, Intended Use & Effectiveness:

This device is a modification of the silicone sleeve in current use. The modification consists of a silicone sleeve that does not contain opaque additives or tints. This clear sleeve allows for transmission of light to the surgical site when coupled to a fiber optic light pipe. The fiber optic light pipe attaches to the side of a phacofragmentation handpiece.

The intended use of this device is to provide illumination to the tip of the phacoemulsification tip cap sleeve to aid in the safe removal of the cataract lens. The illumination that is provided at the tip of the sleeve will provide enhanced visualization within the eye, so the powerful overhead surgical lights that are currently used can have decreased light levels during surgery. The Phaco Illuminator tip cap has the same intended use as many competitive Phaco tip caps already in commercial distribution.

The effectiveness of the device is improved by the source of illumination being at the tip of the instrument rather than only from an outside source. This results in improved illumination and visualization during the phacoemulsification procedure for the physician.

Technological Characteristics:

See attachment "A" for a comparison of the Phaco Illuminator to the predicate device.

Safety:

Numerous safety areas are being investigated and reviewed to ensure

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that the Welch Allyn model #16000 Phaco Illuminator is as safe, or safer than existing similar devices already in commercial distribution. This device offers a potentially lower risk of light exposure to the eye as it minimizes the need for high powered external light sources. Some of the specific safety areas considered are as follows:

Toxicity	-	The infusion sleeve is manufactured of materials that are identical to predicate device materials. They have a history of contact bio-compatibility. This has been established over many years as a widely used method of cataract surgery.
Electrical	-	The #46100 Light Source currently has agency approvals as a surgical light source based on standards from UL 2601-1, CSA C22.2 No. 601.1-M90, and IEC 601-1, 601-1-2, CE, IEC 801-2,3,4,5, EN55011, AS3200.
Light Output	-	Light output levels will be consistent with previous safe use journal publications reflecting similar devices in the field. Reference Stds. ACGIH and Endoscopic Illumination.
Corrosion	-	Device is non-corrosive.
Explosion	-	Highly unlikely; manufactured of non-explosive materials. The lamp is securely contained within the housing.
Surface Temperature	-	All surfaces will be evaluated for patient and practitioner contact.
Mechanical (Sharp Edges)	-	All contact surfaces have been blended and rounded. The shape of the Illuminating Infusion Sleeve has been established over many years as a widely used and safe configuration for cataract surgery.
Safety/Risk	-	A safety and risk analysis will also be performed, ensuring all risks will be reduced to an acceptable level.

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Attachment: "A"

Chart of Predicate Device Comparison

Similarities of the Welch Allyn model #16000 Phaco Illuminator to the Predicate Device Dr. Reynard Phacoilluminator (ref. 510(k) #K964018):

Technical Specifications	**Dr.Reynard Phacoilluminator**	**W.A. #16000 Phaco Illuminator**
Intended use:	Provide illumination at surgical site of intraocular structures	Same
FDA Class:	II	II
Infusion Sleeve Material	Silicone	Same
Illumination:	Light source through fiber optics	Welch Allyn #46100 Xenon Light Source through fiber optics
Sterility:	Conventional methods including autoclave	Disposable - one time use
Design:	Silicone sleeve illuminated by external light source	Same
Where used:	Hospital, Surgical Center	Same
Safety Factors:	Established over many years and widely used method of cataract surgery	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1997

Mr. Colin Wolff
Quality Engineer
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0187

Re: K971750
Trade Name: Welch Allyn #6000
Phaco Illuminator
Regulatory Class: II
Product Code: 86 HQC
Dated: May 2, 1997
Received: May 12, 1997

Dear Mr. Wolff:

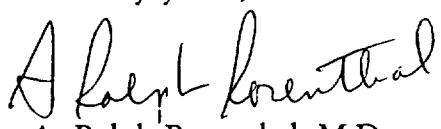
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have 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 requirements, 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) 594-4613. 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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

510(k) Number (if known): K971750

Device Name: Phaco Illuminator

Indications For Use:

Infusion Sleeve for Cataract Surgery Handpieces which also provides illumination.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971750

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)