K990671

MAY 10 1999

Hurricane Medical

Summary of Safety and Effectiveness
Corneal Light Shield

In 1968, Kuwabara et al. demonstrated that light exposure from an ophthalmoscope would cause varying degrees of damage ranging from total degeneration of the whole retina to minimal changes in the photoreceptors. Archives in Ophthalmology, 1968; 79:69-77.

In 1979, Hochheimer et al. first described retinal changes that are caused by exposure to the light from an operating microscope and a slit lamp. American Journal of Ophthalmology, 1979; 88:1039-1044.

Ophthalmic surgeons have been protecting the cornea since about 1979. At that time, they began using paper punch discs of opaque trash bags. In 1984, Schwartz et al introduced an opaque silicone corneal shield. The shield could be used in cataract and lens implantation and may have application for vitrectomy, pterygium, and lid procedures. It was reported that the device was non-toxic to the corneal epithelium. Ophthalmology Times, September 15, 1994, p. 9.

Olander et al. described a variety of corneal occluder materials that include hydrated HEMA, sponge, PMMA, and silicone. Use of the corneal occluder is a simple way to reduce the light exposure delivered to the retina by the operating microscope. The ideal occluder should have a light transmittance close to zero and should be made of a hydrating material. The author reported that he had used corneal occluders for years during routine cases and found them safe and effective. Ophthalmic Surgery, 1991; 22:356-357.

Hurricane Medical corneal light shields are manufactured from non-linting hydrophilic polyvinyl alcohol sponge with a pore size of approximately 100 micron.

Hurricane Medical utilizes Gamma radiation for product sterilization. Processing is in accordance with ISO 11137. The sterilization process is validated periodically and provides a 10^{-6} sterility assurance level (SAL).

Summary of Safety and Effectiveness
Instrument Wipes

Wipes are commonly used to clean surgical instruments and gem blades. The nonlinting types of wipes don't leave debris on the instrument and will not drag on blades or serrated tips.

Hurricane Medical wipes are made from medical grade nonlinting hydrophilic polyvinyl alcohol (PVA) sponge.

Hurricane Medical utilizes Gamma radiation for product sterilization. Processing is in accordance with ISO 11137 and European Standard EN552 for medical device sterilization. The sterilization process is validated periodically and provides a 10^{-6} sterility assurance level (SAL).

Hurricane Medical

Summary of Safety and Effectiveness for
Surgical Spears and Sponges

Surgical spears and sponges were developed by surgical staff to keep the surgical site clean and free from blood and tissue debris. Also, they are used to remove lost vitreous during anterior segment surgery. Ophthalmic Surgery, 1975 Summer; 6(2):58-66.

Later, the nonlinting material polyvinyl alcohol was introduced as a neurosurgical pattie and then incorporated as an ophthalmic microsponge. Journal of Neurosurgery, 54, Feb. 1981.

Hurricane Medical Eye Sponges and Spears are highly absorbent materials designed for absorption of fluids during eye surgery.

Absorbent materials will include hydrocellulose, polyvinyl alcohol, viscose and US-origin cotton.

Hurricane Medical utilizes Gamma radiation for product sterilization. Processing is in accordance with ISO 11137. The sterilization process is validated periodically and provides a 10^{-6} sterility assurance level (SAL).

Hurricane Medical

Summary of Safety and Effectiveness
Fluid Wicks

During eye surgery, it is important to keep the cornea surface moist continuously. This is commonly achieved by dripping saline on the eye at regular intervals. The excess flows and forms a pond in the nasal or temporal canthal triangle. Blanksma et al., Ophthalmic Surgery, 14:501.

Absorption or mechanical removal, which includes aspiration, must handle the fluid runoff, by a catheter connected to a suction pump. Freeman et al., Atlas of Vitreoretinal Surgery, 1990, p. 42-45.

The conjunctiva is contaminated with microorganisms even after washing with antibiotic solution. This creates a danger of the dripping solution back flowing into the surgically opened area which may result in an intraocular infection.

In 1983, Blanksma et al. devised a simple drain constructed from a woven cotton strip that is laid down in the lower fornix and stretched along the side of the face. The device works on capillary action and is adequate for draining fluid away from the surgical site. Ophthalmic Surgery, 14:501.

Hurricane Medical fluid wicks are made from non-linting polyvinyl alcohol (PVA) sponge with a pore size of approximately 100 microns.

Hurricane Medical utilizes Gamma radiation for product sterilization. Processing is in accordance with ISO 11137. The sterilization process is validated periodically and provides a 10^{-6} sterility assurance level (SAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 1999

Mr. David A. Clapp
Regulatory Affairs Head
Official Correspondent
Hurricane Medical
2331K 63rd Avenue East
Bradenton, FL 34203

Re: K990671
Trade Name: Drainage Wick; Surgical Spears and Sponges, Corneal Light
Regulatory Class: II
Product Code: 86 HOZ
Dated: April 13, 1999
Received: April 19, 1999

Dear Mr. Clapp:

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 (for the indications for use stated in the enclosure) 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

510(k) Number : K990671

Device Name: Drainage Wick, Sugical Spears and Sponges, Corneal Light Shield

Indications For Use:

These devices are used to remove excess fluid and debris from the surgical area or instrument. Also, placed on the cornea to moisten the cornea and protect the retina from the intense operating light during ophthalmic surgery.

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

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use X or Over-the –counter use_____

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990671