JAN - 4 2000 K993361

Product Name: Tubing Extension Set
Company: Hurricane Medical
2331K 63rd Avenue East
Bradenton, FL 34203
Phone Number: 941-751-8805
Contact Person: David A. Clapp

Device Classification Name: Replacement tubing for vitrectomy, 886.4150
Device Classification: 86MSR, Class II

Summary Of Safety And Effectiveness

Silicone tubing extension sets have been used for many years in ophthalmic surgery as a means to deliver fluids to the surgical site and aspirate fluids away from the surgical site.

Emery et. al. describes the use of a length of silicone tubing for maintaining the anterior chamber pressure. The length of tubing is attached to a cannula at one end and an infusion bottle on the opposite end. Extracapsular Cataract Surgery, 1983, page 312.

Jaffe et. al. describe the use of a sterile extension set attached to a cystotome on one end and a syringe operated by an assistant at the other for fluid aspiration. Cataract Surgery, 1990, page 83.

The Hurricane Medical tubing extension set consists of a length of silicone tubing with luer taper hubs (one male and one female) attached to both ends.

This device is used by an ophthalmic surgeon to safely and effectively extend the irrigation/aspiration syringe by use of the tubing extension set away from the cannula or ophthalmic surgical instrument allowing better control of irrigation/aspiration during the ophthalmic surgical procedure. This also allows the surgeons assistant to perform the irrigation/aspiration process if needed.

The silicone tubing used is medical grade and meets the USP class VI test for plastics. The male and female luer hub fittings attached to the tubing ends contain a 6% taper to assure proper fit to syringes and other medical devices. The tubing extension set allows free movement of the aspiration/irrigation syringe during the procedure and provides a greater level of control during aspiration/irrigation. The devices are packaged in water impermeable and tear resistant Tyvek/Poly pouches that are heat sealed. The sterilization process ensures at least 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

JAN - 4 2000

Mr. David A. Clapp
Hurricane Medical
2331K 63rd Avenue East
Bradenton, FL 34203

Re: K993361
Trade Name: Tubing Extension Set
Regulatory Class: II
Product Code: 86 MSR
Regulation: 886.1450 (vitrectomy)
Dated: October 1, 1999
Received: October 6, 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

K993361

Device Name: Tubing, Fluid Delivery

Indications for Use:

This device is used by an ophthalmic surgeon to extend the irrigation/aspiration syringe by use of the tubing extension set away from the cannula allowing better control of irrigation/aspiration during the ophthalmic surgical procedure. This also allows the surgeons assistant to perform the irrigation/aspiration process if needed.

(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______

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993361