November 1, 2021

John Branch
Grace Holland
Regulatory Consultant
3722 Ave. Sausalito
Irvine, California 92606

Re: K971134
Trade/Device Name: Vista Eyeshower
Regulatory Class: Unclassified
Product Code: LXQ

Dear Grace Holland:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 4, 1997. Specifically, FDA is updating this SE Letter as an administrative correction. There was a typo in the product code; the correct product code is LXQ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact J. Angelo Green, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6484, Angelo.Green@fda.hhs.gov.

Sincerely,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director for Contact Lenses and Dry Eye Devices
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Branch
c/o Ms. Grace Holland
Holland & Associates
3722 Ave. Sausalito
Irvine, CA 92606

NOV - 4 1997

Re: K971134
Trade Name: Vista EYESHOWER (Single-use, Disposable)
Regulatory Class: Unclassified
Product Code: 86 LXO
Dated: September 4, 1997
Received: September 5, 1997

Dear Mr. Branch:

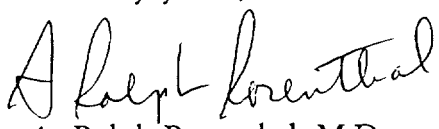
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (if known): K971134

Device Name: Vista EYESHOWER

Indications For Use:

The Vista EYESHOWER is a single-use, disposable device intended for use with Irigate, sterile, isotonic, buffered eye wash (Optopics Laboratories Corp., Fairton, N.J.), supplied in a 1-ounce Boston round bottle for irrigating the eye to help relieve discomfort caused by foreign material, air pollutants, or chlorinated water.

For Over-The-Counter use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971134

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

(Optional Format 1-2-96)