510(K) SUMMARY

K043503

The information contained in this premarket notification 510(k) summary is submitted as required by 21 CFR 807.92(c):

Submitter: VISX, Incorporated
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Contact Person: Alan F. Russell, Ph.D.
Vice President, Regulatory & Clinical Affairs

Date Summary Prepared: December 17, 2004

Device Trade Name: VISX CV SI-1 CustomVue™ Slit Illuminator

Device Common Name: AC-Powered Slit Lamp

Device Classification/Panel: Class II (Special Controls) / Ophthalmic Devices

Identification of Predicate Device: Substantial equivalence is claimed based on the Kowa Portable Slit Lamp, as the predicate device (K954782), with its similar intended use, and its classification as a slit lamp, as defined in 21 CFR 886.1850.

Device Description: The VISX CV SI-1 CustomVue Slit Illuminator consists of the slit illuminator and desktop or wall mount charger unit. The charger unit serves both as a continuous charger as well as a convenient base for the instrument.

The slit illumination is focused onto the corneal surface, which is observed through the operating microscope (of the VISX STAR Excimer Laser System). The length and width of the slit may be altered by the surgeon. The surgeon may also alter the angle of the slit illumination to enhance observation of structural detail. The slit illuminator allows the control of slit width from 0.3 to 2.0 mm and slit length from 2.0 to 10.0 mm via means of sliding control knobs.

Intended Use (Indication for Use): The VISX CV SI-1 CustomVue Slit Illuminator is a diagnostic illumination device intended to facilitate the inspection of the structures of the anterior segment of the eye.

Summary of Non-clinical Studies: Testing for compliance to standards IEC 60601-1, IEC 60601-1-2 and electromagnetic compatibility (EMC) were performed on the VISX CV SI-1 CustomVue Slit Illuminator. In addition, a fault tree analysis (FTA) was conducted to encompass the process of patient exposure and practitioner interface.

Conclusion: Based on non-clinical testing results, the VISX CV SI-1 CustomVue Slit Illuminator has demonstrated that it fully supports the proposed indication for use, and that no new safety and effectiveness questions have been raised by the technological characteristics of this new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

VISX, Inc
c/o Alan F. Russell, Ph.D.
Vice President, Regulatory and Clinical Affairs
3400 Central Expressway
Santa Clara, CA 95051

Re: K043503
Trade/Device Name: VISX CV SI-1 CustomVue™ Slit Illuminator
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 17, 2004
Received: December 20, 2004

Dear Dr. Russell:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE FORM

510(k) Number (if known): K043503

Device Name: **VISX CV SI-1 CustomVue™ Slit Illuminator**

Indications for Use:

The VISX CV SI-1 CustomVue Slit Illuminator is a diagnostic illumination device intended for use to inspect the structures of the anterior segment of the eye.

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 _____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K043503