DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 18, 2015

Volk Optical Inc.
Ms. Meghan M. Leonard
Quality and Regulatory Manager for Volk Optical Inc.
7893 Enterprise Drive
Mentor, Ohio 44060

Re: K151961
Trade/Device Name: Volk Disposable Contact Laser and Diagnostic Lens
Regulation Number: 21 CFR 886.1385
Regulation Name: Lens, Contact, Polymethylmethacrylate (PMMA), Diagnostic
Regulatory Class: Class II
Product Code: HJK
Dated: July 17, 2015
Received: July 20, 2015

Dear Ms. Leonard:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Volk Disposable Contact Laser and Diagnostic Lens

Indications for Use *(Describe)*

The Volk Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) are indicated for use as diagnostic lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ATTACHMENT 6 510(K) SUMMARY

510(k) Owner
Volk Optical Inc.
7893 Enterprise Drive
Mentor, OH 44060
Phone: (440) 942-6161
Contact: Meghan M. Leonard

Submission Correspondent
Meghan M. Leonard
Quality Assurance and Regulatory Affairs Manager
Volk Optical Inc.
7893 Enterprise Drive
Mentor, OH 44060
Phone: (440) 510-0745
Fax: (440) 510-0845
Email: meghan.leonard@volk.com

Date Prepared: July 15, 2015 *(revised July 29, 2015)*

Trade Name of Device
Volk Disposable Contact Laser and Diagnostic Lens

Common or Usual Name
Polymethylmethacrylate (PMMA) diagnostic contact lens

Classification Name and Regulation
Lens, Contact, Polymethylmethacrylate, Diagnostic
21 CFR 886.1385, HJK
Ophthalmic Review Panel

Predicate Device
Quadraspheric Diagnostic Fundus Lens (K943125, Cleared on September 2, 1994)

Device Description
The Volk Disposable Contact Laser and Diagnostic Lenses are a family of diagnostic and therapeutic contact lenses used for eye fundus examinations and therapy of intraocular abnormalities. The family consists of two (2) lenses, including the following: Iridotomy Lens and Capsulotomy Lens.

The family of Volk Disposable Contact Laser and Diagnostic Lenses are designed around the classic Volk Contact Laser and Diagnostic Lenses. Each model lens is similar in design, but provide different optical elements to provide excellent visualization of the ocular anatomical areas for the particular intended use.

The lenses are provided sterile for single use.

Intended Use / Indications for Use
The Volk Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) are indicated for use as diagnostic lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.

Substantial Equivalence
The family of Volk Disposable Contact Laser and Diagnostic Lenses are equivalent to other diagnostic contact lenses as described in 21 CFR Part 886.1385. The principal difference is the packaging and sterilization of the lenses within a sterile pouch. The device modification is being made as a result of a device improvement or enhancement.

The family of Volk Disposable Contact Laser and Diagnostic Lenses are substantially equivalent in design, material, classification, and intended use to the Volk Quadraspheric Fundus Lens (K943125) cleared on 9/2/1994, the Volk Contact Laser & Diagnostic Lenses (K023221) cleared on 10/11/2002, and the Volk Disposable Vitrectomy Lens (K050623) cleared on 5/28/2005, as seen in the chart below.

Comparison	**Volk Disposable Contact Laser and Diagnostic Lenses (current application)**	**Volk Quadraspheric Fundus Lens (K943125)**	**Contact Laser & Diagnostic Lenses (K023221)**	**Volk Disposable Vitrectomy Lenses (K050623)**
Indicated Use	The Volk Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) are indicated for use as diagnostic lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.	The device is indicated for use as a diagnostic contact lens for eye fundus examinations and use in the therapy of intraocular abnormalities.	The device is indicated for use as a diagnostic contact lens for eye fundus examinations and use in the therapy of intraocular abnormalities.	The devices are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities. The devices are sterile, single use, disposable lens systems.

Comparison	Volk Disposable Contact Laser and Diagnostic Lenses (current application)	Volk Quadraspheric Fundus Lens (K943125)	Contact Laser & Diagnostic Lenses (K023221)	Volk Disposable Vitrectomy Lenses (K050623)
Design	Various, including designs for iridotomy and capsulotomy.	Various, including the quadraspheric and other designs representing a range of magnification and field of view.	Various, including designs for iridotomy, capsulotomy, and fundus.	Various designs include the flat, mid field, wide field, and 15°, 30°, and 45° prisms.
Contact Material	PMMA	PMMA and glass	Thermoset polyesterurethane and glass	PMMA
Packaging	Single lens packaged sterile in sterilization pouch	Single lens packaged in a non-sterilizable case	Single lens packaged in a non-sterilizable case	Single lens packaged sterile in sterilization pouch
Sterility	EO Sterilized	Non-sterile	Non-sterile	EO Sterilized

Performance Data

Performance standards for diagnostic contact lenses have not been issued. However, sterilization validation testing was performed, which demonstrated that the Volk Disposable Contact Laser and Diagnostic Lenses met the sterilization requirements specified in the validation protocol. Additionally, shelf life testing was performed, which confirmed a five (5) year shelf life.