DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 23, 2015

Brien Holden Vision Pty Ltd.
Mr. Randall May
Vice President, Regulatory and Quality Affairs
ABN 85 138 617 062
Level 3 North Wing, Rupert Myers Building
Gate 14 Barker Street, UNSW
Sydney NSW 2052, Australia

Re: K143280
Trade/Device Name: BHV VIVID (etafilcon A) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 23, 2015
Received: March 27, 2015

Dear Mr. May:

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" (21 CFR 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,

Deborah L. Falls -S

for Malvina B. Eydelman, MD
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)*
K143280

Device Name
BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*
The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of distance, intermediate and near vision in presbyopic, phakic or pseudo-phakic persons with non-diseased eyes who can have up to approximately 1.50 diopters (D) of astigmatism.
The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye.
Eye care practitioners may prescribe the lenses either for single use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement (see "Wearing Schedule").
When prescribed for single-use disposable wear (see "Wearing Schedule") the BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal. Therefore no cleaning or disinfection is required.
When prescribed for frequent/planned replacement wear the BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed, and disinfected each time the lens is removed. The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens contact lens is to be discarded after the recommended wearing period as prescribed by the eye care practitioner. When prescribed for frequent/planned replacement wear, the lenses should be disinfected using a chemical disinfection system only (i.e., not heat).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

I. Submitter

Manufacturer Name:	Brien Holden Vision Pty Ltd.
Address:	Level 3, North Wing, Rupert Myers Building Gate 14 Barker Street University of New South Wales Sydney, NSW 2052 Australia
Phone:	+61 2 9385 7410
Fax:	+61 2 9385 7401
Contact Person	Randall May
Date Prepared:	11 November 2014

II. Device

Trade Name:	BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens
Common Name:	Daily Wear Soft (Hydrophilic) Contact Lens
Device Class	Class II; Ophthalmic therapeutic device
Classification:	21 CFR 886.5925
Product Codes:	LPL, MVN

III. Predicate Device

Primary Predicate

VISTAKON® (etafilcon A) Soft (Hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear (K062614)

This predicate has not been subject to a design-related recall.

Reference Device

PEGAVISION CORPORATION Aquamax (Etafilcon A) Bi-Weekly and Daily Disposable Soft (Hydrophilic) Contact Lenses (K120028**)**

This reference device has not been subject to a design-related recall.

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www.brienholdenvision.com

IV. Device Description

The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is an extended depth-of-focus (EDOF) contact lens for the daily wear correction of distance, intermediate and near vision in presbyopic persons.

The lens material, etafilcon A, is a random co-polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which were cross-linked with ethylene glycol dimethacrylate (EGDMA) and 1,1,1 -trimethylolpropane trimethacrylate (TMPTMA) via photo-polymerization. These lenses are tinted blue using color additive Reactive Blue No. 19 to make them more visible for handling. These lenses contain UV blocker, a benzotriazole UV absorbing monomer to block UV radiation. The average transmittance characteristics of theses lenses are less than 5 % in the UVB range of 280-315 nm and less than 30% in the UVA range of 315-380 nm. Lenses are supplied sterile in sealed blister package containing sterile isotonic borate buffered saline solution.

V. Indications for Use

The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of distance, intermediate and near vision in presbyopic, phakic or pseudo-phakic persons with non-diseased eyes who can have up to approximately 1.50 diopters (D) of astigmatism.

The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye care practitioners may prescribe the lenses either for single use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement (see “Wearing Schedule”).

When prescribed for single-use disposable wear (see “Wearing Schedule”) the BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal. Therefore no cleaning or disinfection is required.

When prescribed for frequent/planned replacement wear the BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed, and disinfected each time the lens is removed. The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens contact lens is to be discarded after the recommended wearing period as prescribed by the eye care practitioner. When prescribed for frequent/planned replacement wear, the lenses should be disinfected using a chemical disinfection system only (i.e., not heat).

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VI. Predicate Device Comparison

The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lenses have similar intended use indications and technological characteristics of the primary predicate device and reference device listed above.

Table 8.1 Subject and Primary Predicate Device Comparison

Characteristic	BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lenses	VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear [Primary Predicate]
510(k) Number	**Subject Device**	**K062614**
FDA Group	Group IV > 50% water, ionic polymer	Group IV > 50% water, ionic polymer
USAN Name	etafilcon A	etafilcon A
Production Method	Cast Molding	Cast Molding
Water Content	58%	58%
Refractive Index	1.402	1.40
Power (Diopter)	+20.00D to -20.00D	+20.00D to -20.00D
Base Curve Radius (mm)	7.85 to 10.0	7.85 to 10.00
Diameter (mm)	12.0 to 15.0	12.0 to 15.0
Centre Thickness (mm)	Varies with power: 0.060 to 0.500 mm	Varies with power: 0.060 to 1.00 mm

The subject device complies with the following recognised consensus standards:

- ISO 18369-1 First edition 2006-08-15 Ophthalmic optics -- Contact lenses -- Part 1: Vocabulary, classification system and recommendations for labeling specifications [Including: Amendment 1 (2009)]
- ISO 18369-2 Second edition 2012-12-01 Ophthalmic optics -- Contact lenses -- Part 2: Tolerances
- ISO 18369-3 First edition 2006-08-15 Ophthalmic optics - Contact lenses - Part 3: Measurement Methods

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- ISO 18369-4 First edition 2006-08-15 Ophthalmic optics - contact lenses - Part 4: Physicochemical properties of contact lens materials
- ASTM F1980 – 07 (Reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-2:2009 Sterilization of medical devices – Microbiological methods – Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 17665-1:2006 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

VII. Summary of Non-clinical Testing

All tests were conducted in accordance with the FDA *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact lenses*, May 12, 1984:

- Bench Testing
- Biocompatibility
- Microbiology
- Bacteriostatic Validation
- Leachables

VIII. Clinical Testing

The technological characteristics, formulation, manufacturing and sterilization processes are substantially equivalent to the predicate devices, therefore no clinical data is required.

IX. Conclusions

The BHV VIVID (etafilcon A) Soft (Hydrophilic) Contact Lens is substantially equivalent to the predicate devices for the labeled indications for use. Successful results from chemical/physical, stability, and toxicology tests further confirmed the lenses are within established finished product specifications, remain stable, and are non-toxic and biocompatible with the ocular environment.

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