May 26, 2021

OTE North America LLC
% Ellen M. Beucler
Vice President
Foresight Regulatory Strategies, Inc.
1820 Turnpike Street, Suite 201
North Andover, MA 01845

Re: K210051
Trade/Device Name: OTE MPS 045 Multi-purpose Lens Care Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: April 19, 2021
Received: April 21, 2021

Dear Ellen M. Beucler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210051

Device Name

OTE MPS 045 Multi-Purpose Lens Care Solution

Indications for Use *(Describe)*

OTE MPS 045 Multi-Purpose Lens Care Solution is indicated for daily cleaning, chemical (not heat) disinfection, conditioning, rinsing and storage of hydrogel and silicone hydrogel soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

OTE MPS 045
Multi-Purpose Lens Care Solution

1. Applicant Information

OTE NORTH AMERICA LLC
40 Bayview Ave.
Inwood, New York, USA 11096

Contact Person: Nathan Rosenberg
Telephone No.: 516-371-0225
Email: nathan@oteamerica.com
Date Prepared: May 23, 2021

2. Device Information

Device classification:	Class II
Classification name:	21 CFR 886.5928 Soft (hydrophilic) Contact Lens Care Product
Proprietary name:	OTE MPS 045 Multi-Purpose Lens Care Solution
Product code:	LPN

3. Predicate Device

OTE North America claims substantial equivalence to K083757 Bausch & Lomb® BPZ02, commercially distributed as Biotrue® Multi-Purpose Solution.

4. Description of Device

OTE MPS 045 Multi-Purpose Lens Care Solution is a sterile, buffered aqueous solution that contains sodium hyaluronate, poloxamer 407, boric acid, sodium borate, propylene glycol, and is preserved with Polyaminopropyl Biguanide Hydrochloride 0.00002%, Polyquaternium-2 0.00043%, and edetate disodium.

5. Indications for Use

OTE MPS 045 Multi-Purpose Lens Care Solution is indicated for daily cleaning, chemical (not heat) disinfection, conditioning, rinsing and storage of hydrogel and silicone hydrogel soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

6. Performance Data

Non-Clinical Data

A series of tests were performed to demonstrate the substantial equivalence of the OTE MPS 045 Multi-Purpose Lens Care Solution to the predicate device. All tests were conducted in accordance with the Premarket Notification 510(k) Guidance Document for Contact Lens Care Products (1997), ISO Standards or valid scientific protocols.

- Lens Compatibility
  Compatibility testing was conducted with six commercially available hydrogel and silicone hydrogel soft contact lenses: Acuvue 2 (etafilcon A), Clarity 56 % 1 Day (somofilcon A), Biofinity Energys (comfilcon A), Air Optix Aqua (lotrafilcon B), Acuvue Vita (senofilcon C) and PureVision (balafilcon A). Results demonstrated that the OTE MPS 045 Multi-Purpose Lens Care Solution was compatible with the test contact lenses.

- Disinfecting and Preservative Efficacy
  Disinfecting efficacy testing was conducted to evaluate the antimicrobial activity of the OTE MPS 045 Multi-Purpose Lens Care Solution as a contact lens disinfection product. Results demonstrated that harmful microorganisms were effectively reduced to an effective level at 6 and 24 hours. In addition, Preservative Efficacy testing was conducted to support the 3-month open bottle discard date of the OTE MPS 045 Multi-Purpose Lens Care Solution.

- Cleaning Efficacy
  Cleaning Efficacy was evaluated in an in-vitro system to determine the Critical Micelle Concentration (CMC) of the OTE MPS 045 Multi-Purpose Lens Care Solution. The concentration of the surfactants is above the CMC of the solution.

- Toxicology

A series of in-vitro and in-vivo biocompatibility tests were conducted in accordance with the GLP regulation (21 CFR Part 58) and ISO biocompatibility standards to ensure the safety of the OTE MPS 045 Multi-Purpose Lens Care Solution and the packaging components.

Biocompatibility testing for the container components was conducted in compliance with the following standards.

- 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies
- ISO10993-5, 2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO10993-10, 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO10993-11, 2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

Biocompatibility testing for the OTE MPS 045 Multi-Purpose Lens Care Solution was conducted in compliance with the following standards.

- 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies
- ISO10993-5, 2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO10993-10, 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO10993-11, 2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO18189, 2016(E), Ophthalmic optics – Contact Lens and Contact Lens Care Products – Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interaction.
- ISO9394, 2012, Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes

Results of all biocompatibility testing demonstrated that the solution and packaging components are non-toxic, non-irritating and non-sensitizing.

Clinical Data

Study Design

A clinical study was conducted comparing OTE MPS 045 Multi-Purpose Lens Care Solution to Bausch & Lomb Biotrue Multi-Purpose solution when used daily for cleaning, disinfecting and conditioning hydrogel and silicone hydrogel soft contact lenses. This study was a double-masked (Investigator and Subject), multi-center, randomized, concurrent control study with a duration of 30 days (1 month) and 199 subjects.

Study End Points

Primary Safety Endpoints: Non Inferiority of slit lamp findings, limbal hyperemia, bulbar hyperemia and corneal staining. The safety endpoint was supported by the study findings.

Primary Effectiveness Endpoints: Non Inferiority of comfort, visual acuity, surface wettability, lens deposits. At each visit, OTE MPS 045 Multi-Purpose Lens Care Solution was non-inferior to BioTrue with respect to wettability and film deposits. The efficacy endpoint was supported by the study findings.

Safety (Adverse Events)

Adverse events were reported in ten subjects. Six subjects had symptoms that were mild/non-significant, one subject had symptoms that were moderate and significant, and three subjects had non-device related adverse events. All adverse events had resolved before the end of the study.

Clinical Summary

The purpose of the study was to evaluate the clinical performance of the contact lens care solution OTE MPS 045 in comparison with BioTrue® (Bausch & Lomb) Multi-purpose contact lens care solution in a representative population of soft contact lens wearers. The Primary Safety and Effectiveness endpoints were supported by the study data. Therefore, the OTE MPS 045 Lens Care Solution is substantially equivalent to the predicate, BioTrue® (Bausch & Lomb) Multi-purpose contact lens care solution.

Conclusion

Based upon the data presented, the OTE MPS 045 Multi-Purpose Lens Care Solution is as safe, as effective and performs as well as the predicate device.

7. Substantial Equivalence

The claim of substantial equivalence to the previously cleared device is supported by the non-clinical data, clinical data and the Comparison of Characteristics in Table 1.

Table 1 Comparison of Characteristics

Product Name	OTE MPS 045 Multi-Purpose Solution	BioTrue Solution Multi-Purpose Solution
510(k) #	–	**K083757**
FDA Product Code	LPN	LYL
Classification	Class II (21 CFR 886.5928)	Class II (21 CFR 886.5928)
Intended Use	OTE MPS 045 Multi-Purpose Lens Care Solution is indicated for daily cleaning, chemical (not heat) disinfection, conditioning, rinsing and storage of hydrogel and silicone hydrogel soft (hydrophilic) contact lenses as recommended by your eye care practitioner.	Bausch & Lomb® BPZ02 Multi-Purpose Solution is indicated for use in the daily conditioning, cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.
For Use With	Hydrogel and Silicone Hydrogel Soft (hydrophilic) Contact Lenses	Hydrogel and Silicone Hydrogel Soft (hydrophilic) Contact Lenses
Dual Preservatives	Polyaminopropyl Biguanide Hydrochloride, Polyquaternium-2	Polyaminopropyl Biguanide Hydrochloride, Polyquaternium-1
Buffer System	Sodium Borate, Boric Acid	Sodium Borate, Boric Acid
Disinfection Cycle	At least 6 hours	At least 4 hours
Lubricating Agent	Sodium Hyaluronate	Sodium Hyaluronate
Target Population	Home personal use	Home personal use
Sterile	Yes	Yes
CE Mark	Yes	Yes
Appearance	Clear, Colorless Solution free of particles	Clear, Colorless Solution free of particles
pH	7.2 - 7.4	7.5
Osmolarity	300-330 mOsm/kg	–