August 27, 2025

UV One Hygienics, Inc.
Dora Suppes
CEO
Banner Desert Hospital Medical Campus
1432 S. Dobson Road, Ste. 202
Mesa, Arizona 85202

Re: K251068
Trade/Device Name: KnoxFog Anti-fogging Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCT
Dated: March 17, 2025
Received: April 7, 2025

Dear Dora Suppes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.08.27 14:51:31 -04'00'

Colin Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251068

Device Name
KnoxFog Anti-fogging Device

Indications for Use *(Describe)*
The KnoxFog™ Anti-fogging Device is a temporary anti-fog coating and therein inhibits fogging on optical lenses. It is a laparoscopic accessory intended to facilitate intraoperative defogging of laparoscope lenses, thereby maintaining visualization of the surgical site and closed body cavity.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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March 12, 2025 12:48 PM

DEVICE SUMMARY		
Document Title	Document Description	Version No.
KF-25-KFDS	KnoxFog™ Device Summary	Final

510(k) SUMMARY

Submitter Information

- **Name:** UV ONE Hygienics, Inc.
- **Address:** 1432 S. Dobson Rd. Ste. 202, Mesa, AZ 85202
- **Contact Person:** Dora Suppes, CEO
- **Phone:** 480-221-4712
- **Email:** dora@uvonetech.com/dorasuppes@gmail.com
- **Date Prepared:** March 12, 2025

Device Information

- **Trade Name:** KnoxFog™
- **Common Name:** Anti-fog solution for endoscopic lenses
- **Classification Name:** Endoscope and accessories (21 CFR 876.1500)
- **Regulatory Class:** Class II
- **Product Code:** OCT (Anti-Fog Solution and Accessories, Endoscopy)

Predicate Device

VitreOx™ (K163257)

Device Description

KnoxFog™ is a semi-sol gel anti-fog coating designed to prevent condensation on endoscopic lenses during surgical procedures. The device is supplied as a sterile solution in single-use containers for application immediately prior to endoscopic procedures. When applied to the endoscope lens, KnoxFog™ forms a transparent hydrophilic coating that prevents fog formation by maintaining optical clarity in high-humidity environments. The product is terminally sterilized using gamma radiation to ensure safety for use in surgical environments.

Indications for Use

KnoxFog™ is intended for use as an anti-fog solution applied to rigid endoscope lenses prior to insertion into the body to maintain optical clarity during endoscopic procedures.

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DEVICE SUMMARY		
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Technological Characteristics

KnoxFog™ utilizes a semi-sol gel formulation that transforms into a solid-phase film upon application to the endoscope lens. This creates a hydrophilic surface that prevents water condensation (fogging) when the lens encounters temperature differentials and humid environments typical of endoscopic procedures.

Performance Data

Bench testing was conducted to establish substantial equivalence to the predicate device. Testing included:

1. **Time-to-Fog Analysis:** Comparative testing demonstrated that KnoxFog™-treated endoscope lenses remained fog-free for an average of 71.6 ± 3 minutes compared to 62 ± 5.5 minutes for VitreOx™-treated lenses, representing 117% relative performance compared to the predicate device.
2. **Transportation Testing:** Simulated shipping and handling testing verified product stability under various transportation conditions.
3. **Accelerated Aging:** Six-month accelerated aging studies confirmed product shelf-life claims.
4. **Biocompatibility Testing:** Testing in accordance with ISO 10993 standards demonstrated that KnoxFog™ is biocompatible for its intended use, with comprehensive assessment addressing previous cytotoxicity concerns.

Conclusion

Based on the comparative performance testing and technological characteristics, KnoxFog™ is substantially equivalent to the legally marketed predicate device, VitreOx™ (K163257). Testing demonstrates that KnoxFog™ performs as intended and does not raise new questions of safety or effectiveness.