May 09, 2025

Tristel Solutions Ltd.
Véronique Li
Unit 1b, Lynx Business Park, Fordham Road
Snailwell
Cambridgeshire, CB8 7NY
United Kingdom

Re: K242732
Trade/Device Name: Tristel OPH
Regulation Number: 21 CFR 880.6886
Regulation Name: Foam Or Gel Chemical Sterilant/High Level Disinfectant
Regulatory Class: Class II
Product Code: QWS
Dated: September 10, 2024
Received: April 8, 2025

Dear Véronique Li:

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,

Katharine Segars -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control
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.

Submission Number *(if known)*

K242732

Device Name

Tristel OPH

Indications for Use *(Describe)*

Tristel OPH is a high level disinfectant foam for reprocessing ophthalmic devices. It can be used to high level disinfect devices that may contact mucous membranes during use, such as diagnostic and laser lenses, tonometer prisms, pachymeters, retinal imaging probes, A-scan and B-scan probes.

Tristel OPH is a high level disinfectant when used in accordance with the Directions for Use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above Minimum Recommended Concentration (MRC).

Tristel OPH Foam must be applied on the surface of an ophthalmic device using Tristel OPH Wipes.

Tristel OPH Wipes are intended for application of Tristel OPH Foam on the surface of ophthalmic devices and to remove residue of the foam after high level disinfection.

Each dose of Tristel OPH Foam and each Tristel OPH Wipe are single use.

The semi-critical ophthalmic devices processed by Tristel OPH must first be cleaned according to a validated cleaning protocol or standard and following the device manufacturers' instructions. Tristel OPH Foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC.

Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel OPH may be verified using Tristel Test Strips.

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.

Unit 1b, Lynx Business Park, Fordham Road,
Snailwell, Cambs, CB8 7NY, UK
T +44 (0)1638 721500
E mail@tristel.com
@TristelGlobal
www.tristel.com
Tristel Solutions Ltd Company No. 03518312 Tristel plc Company No. 04728199 Registered office As above

510(k) Summary K242732

I. SUBMITTER

Tristel Solutions Ltd.
Tristel Solutions Ltd., Unit 1B, Lynx Business Park,
Fordham Road, Snailwell, Cambridgeshire,
CB8 7NY, United Kingdom Phone:
+44 (0)1638 721500

Contact Person: Julija Shabanova
Tristel Solutions Ltd., Unit 1B, Lynx Business Park,
Fordham Road, Snailwell, Cambridgeshire,
CB8 7NY, United Kingdom
Ph. +44 (0)1638 721500
Em. julijashabanova@tristel.com

Date Prepared: May 9, 2025

II. SUBJECT DEVICE

Brand Name: Tristel OPH
Common Name: High Level Disinfectant
Classification Name: Foam or gel chemical sterilant/high level disinfectant
Regulation Number: 21 CFR 880.6886
Product Code: QWS
Regulatory Class: II

III. PREDICATE DEVICE

Predicate Device: Tristel Duo ULT (DEN220041)

IV. DEVICE DESCRIPTION

Tristel OPH is a high level disinfectant foam for reprocessing ophthalmic devices. It can be used to high level disinfect devices that may contact mucous membranes during use, such as diagnostic and laser lenses, tonometer prisms, pachymeters, retinal imaging probes, and A-scan and B-scan probes.

Tristel OPH Foam is packaged in a hand-held dispenser bottle (**Figure 1**). Tristel OPH Foam is made of two solutions, Tristel OPH Activator solution and Tristel OPH Base solution, which are mixed when dispensed to generate active ingredient chlorine dioxide. In- use concentration of chlorine dioxide (ClO2) is 0.032% (320ppm).

Tristel OPH Foam Activator and Base solutions are contained in a dual compartment bottle with a dispenser pump and are ready to use (**Figure 2**).

Figure 1. Pictures of the packaged Tristel OPH

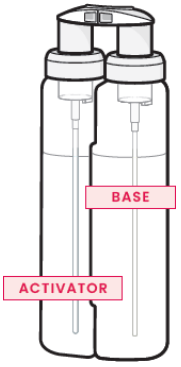

Figure 2. Schematic of Tristel OPH Foam bottle

Tristel OPH Foam is supplied with Tristel OPH Wipes. Tristel OPH Wipes are dry wipes made of a non-woven and low-linting material. Tristel OPH Wipes are intended to apply Tristel OPH Foam on the surface of ophthalmic devices and to remove residue of the foam after high level disinfection once the contact time of 2 minutes has elapsed.

Each dose of Tristel OPH Foam and each Tristel OPH Wipe are single-use.

Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel OPH may be verified using Tristel Test Strips.

V. INDICATIONS FOR USE

Tristel OPH is a high level disinfectant foam for reprocessing ophthalmic devices. It can be used to high level disinfect devices that may contact mucous membranes during use, such as diagnostic and laser lenses, tonometer prisms, pachymeters, retinal imaging probes, A-scan and B-scan biometry probes.

Tristel OPH is a high level disinfectant when used in accordance with the Directions for Use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above the Minimum Recommended Concentration (MRC).

Tristel OPH Foam must be applied on the surface of an ophthalmic device using Tristel OPH Wipes. Tristel OPH Wipes are intended for the application of the Tristel OPH Foam on the surface of ophthalmic devices and to remove residue of the foam after high level disinfection.

Each dose of Tristel OPH Foam and each Tristel OPH Wipe are single use.

The semi-critical ophthalmic devices processed by Tristel OPH must first be cleaned according to a validated cleaning protocol or standard and following the device manufacturers' instructions. Tristel OPH Foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC.

Minimum Recommended Concentration (MRC): ~90% v/v (280ppm) at point of use. MRC of Tristel OPH may be verified using Tristel Test Strips.

Both the subject and the predicate devices have the same intended use for the high level disinfection of semi-critical devices. The Indications for Use differ only in the types of semi-critical devices intended to be disinfected. The differences do not alter the intended.

Table 1 – Predicate Device Tristel Duo ULT and Tristel OPH Indications for Use Comparison Table

	Tristel Duo ULT (DEN220041)	Tristel OPH (K242732)
Indications for Use:	Tristel Duo ULT is a high level disinfectant foam for reprocessing ultrasound probes. It can be used to high level disinfect endocavity transvaginal and transrectal probes, and skin surface transducers that may contact non- intact skin during use. Tristel Duo ULT is a high level disinfectant when used in accordance with the Directions for Use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above Minimum Recommended Concentration (MRC). Tristel Duo ULT Foam must be applied on the surface of an ultrasound probe using Tristel Duo Wipes. Tristel Duo Wipes are intended for application of Tristel Duo ULT Foam on the surface of ultrasound probes and to remove residue of the foam after high level disinfection. Each dose of Tristel Duo ULT Foam and each Tristel Duo Wipe are single use. The semi-critical ultrasound probes processed by Tristel Duo ULT must first be cleaned according to a validated cleaning protocol or standard and following the	Tristel OPH is a high level disinfectant foam for reprocessing ophthalmic devices. It can be used to high level disinfect devices that may contact mucous membranes during use, such as diagnostic and laser lenses, tonometer prisms, pachymeters, retinal imaging probes, A-scan and B-scan probes. Tristel OPH is a high level disinfectant when used in accordance with the Directions for Use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above Minimum Recommended Concentration (MRC). Tristel OPH Foam must be applied on the surface of an ophthalmic device using Tristel OPH Wipes. Tristel OPH Wipes are intended for application of Tristel OPH Foam on the surface of ophthalmic devices and to remove residue of the foam after high level disinfection. Each dose of Tristel OPH Foam and each Tristel OPH Wipe are single use. The semi-critical ophthalmic devices processed by Tristel OPH must first be cleaned according to a validated cleaning protocol or standard and following the

	Tristel Duo ULT (DEN220041)	Tristel OPH (K242732)
	device manufacturers' instructions. Tristel Duo ULT Foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC. Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel Duo ULT may be verified using Tristel Test Strips.	device manufacturers' instructions. Tristel OPH Foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC. Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel OPH may be verified using Tristel Test Strips.

VI. TECHNOLOGICAL CHARACTERISTIC COMPARISON

A side-by-side comparison of the technological characteristics of the predicate device and Tristel OPH is shown in **Table 2.**

Table 2 – Predicate Device Tristel Duo ULT and Tristel OPH Technological Characteristics Comparison Table

	Tristel Duo ULT (DEN220041)	Tristel OPH (K242732)	Comparison
General			
Active Chemistry:	Chlorine dioxide	Chlorine dioxide	Same
Active Concentration:	~320ppm	~320ppm	Same
Purpose:	To achieve high level disinfection by destroying viable forms of microbial life, when used according to labeling	To achieve high level disinfection by destroying viable forms of microbial life, when used according to labeling	Same
Labeling:	High Level Disinfectant Foam	High Level Disinfectant Foam	Same
No. of Foam Doses Required for Each Use:	4	2	Smaller ophthalmic devices require less volume of foam
Prescription Device:	Yes	Yes	Same
Human Factors:	Dispensed ready-to-use foam and applied by a wipe	Dispensed ready-to-use foam and applied by a wipe	Same
Design, Construction, Components:	Aqueous solutions contained in two separate reservoirs within a single dispenser apparatus and mixed together when dosed onto a Tristel Wipe	Aqueous solutions contained in two separate reservoirs within a single dispenser apparatus and mixed together when dosed onto a Tristel Wipe	Same
Reuse Characteristics:	Each dose of Tristel Duo ULT Foam and each Tristel Duo Wipe are single use.	Each dose of Tristel OPH Foam and each Tristel OPH Wipe are single use.	Same
Chemical Indicator:	Tristel Test Strips	Tristel Test Strips	Same

	Tristel Duo ULT	Tristel OPH	Comparison
Contact Time for HLD:	2 minutes at room temperature	2 minutes at room temperature	Same
Mode of Action:	Chemical oxidation of biomolecules, including the cell membrane and nucleic acids.	Chemical oxidation of biomolecules, including the cell membrane and nucleic acids.	Same
Packaging:	Tristel Duo ULT Foam Activator and Base solutions are contained in a dual compartment bottle with a dispenser pump and are ready to use.	Tristel OPH Foam Activator and Base solutions are contained in a dual compartment bottle with a dispenser pump and are ready to use.	Same
Stability			
Shelf Life:	2 years unopened Shelf life 6 month opened Shelf life	2 years unopened Shelf life 6 month opened Shelf life	Same
Transport Stability:	Conditions encountered for global road, sea, and air freight have no effect on product performance.	Conditions encountered for global road, sea, and air freight have no effect on product performance.	Same
Wipes			
Physical Characteristics:	Dry, non-woven, and low-linting	Dry, non-woven, and low-linting	Same
No. of Wipes Supplied:	Pack variant specific (e.g. 200)	Pack variant specific (e.g.310)	Pack variant specific
Linting Tests:	<4 log coefficient of linting	<4 log coefficient of linting	Same
Abrasion Tests:	Withstand a minimum of 200 revolutions	Withstand a minimum of 200 revolutions	Same
Compatibility with Tristel Foam:	Compatible	Compatible	Same

The subject device and its predicate device have an identical intended use and minimal difference in technological characteristics.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing

In addition to the non-clinical performance testing carried out on Tristel Duo ULT which are applicable to Tristel OPH, additional non-clinical performance testing for the intended ophthalmic use pattern were performed using the same test methods used to verify the predicate device. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Table 3 - Predicate Device Tristel Duo ULT and Tristel OPH Non-Clinical Testing Comparison Table

	Tristel Duo ULT	Tristel OPH	Comparison
Potency			
Bactericidal Efficacy: AOAC 955.15, 964.02 and 955.14	Bactericidal against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* in 2.0 minutes exposure at 20°C.	Bactericidal against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* in 2.0 minutes exposure at 20°C.	Same
Fungicidal Efficacy: AOAC 955.17	Fungicidal against *Trichophyton interdigitale* in 1.0 minute exposure at 20°C.	Fungicidal against *Trichophyton interdigitale* in 1.0 minute exposure at 20°C.	Same
Virucidal Efficacy: ASTM E1053	Virucidal against Poliovirus type 1, Herpes simplex virus type 1, Adenovirus type 5 and Feline calicivirus in 30 seconds exposure at 20°C.	Virucidal against Poliovirus type 1, Herpes simplex virus type 1, Adenovirus type 5 and Feline calicivirus in 30 seconds exposure at 20°C.	Same
Mycobactericidal Efficacy: Ascenzi et al., 1987	Mycobactericidal against *Mycobacterium terrae* in 1.0 minute exposure at 20°C.	Mycobactericidal against *Mycobacterium terrae* in 1.0 minute exposure at 20°C.	Same
Sporicidal Efficacy: AOAC 966.04	Sporicidal against *Clostridium sporogenes* and *Bacillus subtilis* in 12 hours exposure at 20°C.	Sporicidal against *Clostridium sporogenes* and *Bacillus subtilis* in 12 hours exposure at 20°C.	Same
Additional Clinically Relevant Efficacy:	Passes AOAC and ASTM1053 against clinically relevant bacteria and viruses. *Candida albicans*, Human hepatitis B virus surrogate (duck hepatitis B virus), Human immunodeficiency virus type 1, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Streptococcus agalacticae*, Carbapenem-resistant *Klebsiella pneumoniae*, Extended Spectrum Beta-Lactamase (ESBL) *Escherichia coli*. Tristel Duo ULT inactivates Human papillomavirus (HPV) type 16 and type 18.	Passes AOAC and ASTM1053 against clinically relevant bacteria, fungi and viruses. *Candida albicans*, *Aspergillus brasiliensis*, *Streptococcus agalacticae*, Carbapenem-resistant *Klebsiella pneumoniae*, Extended Spectrum Beta-Lactamase (ESBL) *Escherichia coli*, *Haemophilus influenza*, Vancomycin-Resistant *Enterococcus faecalis* (VRE), Multi-Drug Resistant *Streptococcus pneumoniae*, *Staphylococcus epidermidis*, Human Coronovirus SARS-CoV-2, Human hepatitis B virus surrogate (duck hepatitis B virus), Human immunodeficiency virus type 1, Influenza A Virus. Tristel OPH inactivates Human papillomavirus (HPV) type 16 and type 18.	Different additional organisms tested depending on clinical area of use

	Tristel Duo ULT	Tristel OPH	Comparison
Simulated-Use			
Summary:	Provides >6 log reduction mycobactericidal efficacy on worst-case inoculated devices in <2 minutes exposure at 20°C at end of self-life, and of use-life and MRC.	Provides >6 log reduction mycobactericidal efficacy on worst- case inoculated devices in <2 minutes exposure at 20°C at end of shelf-life, end of use-life and MRC.	Different devices tested depending on clinical area of use
In-Use			
Summary:	No evidence of growth of wild type bacteria or fungi recovered from devices following disinfection on clinically used instruments	No evidence of growth of wild type bacteria or fungi recovered from devices following disinfection on clinically used instruments	Different devices tested depending on clinical area of use
Compatibility			
Device Compatibility:	Tristel Duo ULT was tested and approved by several device manufacturers and included in the List of Compatible disinfectants. Tristel Duo ULT does not produce any corrosion or other visible damage in the devices and materials tested.	Tristel OPH was tested and approved by several device manufacturers and included in the List of Compatible disinfectants. Tristel OPH does not produce any corrosion or other visible damage in the devices and materials tested.	Different devices/ materials tested depending on clinical area of use
Biocompatibility Toxicity			
Summary:	Testing was conducted following ISO 10993-5 and ISO 10993-10. Tristel Duo ULT foam is non-mutagenic, non-clastogenic in maturing erythrocytes, and non-oral toxic. It is not a skin sensitizer. It is classified as a slight irritant to the skin and an eye irritant in direct contact. In use with the Tristel Duo Wipe, Tristel Duo ULT foam is not considered to have a cytotoxic effect, is negligible irritating to the skin and has no sensitizing potential.	Testing was conducted following ISO 10993-5 and ISO 10993-10. Tristel OPH foam is non-mutagenic, non-clastogenic in maturing erythrocytes, and non-oral toxic. It is not a skin sensitizer. It is classified as a slight irritant to the skin and an eye irritant in direct contact. In use with the Tristel OPH Wipe, Tristel OPH foam is not considered to have a cytotoxic effect, is negligible irritating to the skin and has no sensitizing potential.	Same

	Tristel Duo ULT	Tristel OPH	Comparison
Residues			
Residue Extractable and Leachable:	Residue testing was performed to quantify any residuals remaining/extracted/leached after disinfection with Tristel Duo ULT. The treated device was extracted, and the eluates analyzed for residual components. The results show that Tristel Duo ULT germicide poses no additional risk to the patient or user of the device.	Residue testing was performed to quantify any residuals remaining/extracted/leached after disinfection with Tristel OPH. The treated device/materials were extracted, and the eluates analyzed for residual components. The results show that Tristel OPH germicide poses no additional risk to the patient or user of the device.	Different devices tested depending on clinical area of use
Biocompatibility of Residues:	Any potential residues remaining post reprocessing are non-irritating to dermal, vaginal and rectal tissues.	Any potential residues remaining post reprocessing are non-irritating to dermal and eye tissues.	Different testing depending on clinical area of use
Inhalation			
Inhalation:	Tristel Duo ULT was evaluated for inhalation exposure during use. In a study simulating 40 disinfection procedures, the average 8-hour TWA readings did not exceed the U.S. OSHA permissible exposure limit of 0.1ppm for chlorine dioxide, and the results of the average 15-minute STEL readings did not exceed the California Division of Occupational Safety and Health PEL of 0.3ppm.	Tristel OPH was evaluated for inhalation exposure during use. In a study simulating 51 disinfection procedures, the average 8-hour TWA readings did not exceed the U.S. OSHA permissible exposure limit of 0.1ppm for chlorine dioxide, and the results of the average 15-minute STEL readings did not exceed the California Division of Occupational Safety and Health PEL of 0.3ppm.	Different testing depending on clinical area of use
Human Factors and Usability Engineering			
Summary:	Tristel Duo ULT has been evaluated for the intended users, uses, and use environments.	Tristel OPH has been evaluated for the intended users, uses, and use environments.	Same

VIII. CONCLUSION

The information on technological characteristics and data from non-clinical performance studies establish that the subject device, Tristel OPH, is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device.