July 24, 2026

Eyekon Medical, Inc.
℅ Robert Lundberg
President
OneRA, LLC
2043 Evanston Cir.
Corona, California 92881

Re: K261312
Trade/Device Name: Temporary Keratoprosthesis (QuickSet TKP™)
Regulation Number: 21 CFR 886.3400
Regulation Name: Keratoprosthesis
Regulatory Class: Class II
Product Code: MLP
Dated: April 21, 2026
Received: April 21, 2026

Dear Robert Lundberg:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261312

Please provide the device trade name(s).

Temporary Keratoprosthesis (QuickSet TKP™)

Please provide your Indications for Use below.

The QuickSet Temporary Keratoprosthesis (QuickSet TKP™) is a surgical aid to provide a transparent optical pathway that permits closed pars plana vitrectomy in eyes with abnormal corneas.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Submitter Information

Company: EyeKon Medical, Inc.
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Date Prepared: 23 July 2026

Device Information

Device Trade Name:	QuickSet Temporary Keratoprosthesis (QuickSet TKP™)
Device Common Name:	Keratoprosthesis
Classification Regulation:	21 CFR 886.3400
Classification Name:	Keratoprosthesis, Temporary Implant, Surgical Use
Device Class:	Class II
Device Regulation Panel:	Ophthalmic
Product Code:	MLP

Predicate/Reference Devices

Device Trade Name:	Landers Wide Field Temporary Keratoprosthesis
Device Common Name:	Keratoprosthesis
Classification Regulation:	21 CFR 886.3400
Classification Name:	Keratoprosthesis, Temporary Implant, Surgical Use
Device Class:	Class II
Device Regulation Panel:	Ophthalmic
Product Code:	MLP

Device Description

The QuickSet TKP™ allows for visualization of intraocular structures during combined corneal and vitreoretinal surgery. This indication is useful in preventing the delay of posterior segment treatment, especially in the setting of ocular trauma where corneal visibility is often limited from corneal blood staining, large edematous corneal wounds, or corneal explosive injury with corneal foreign bodies. Common concurrent vitreoretinal procedures include pars plana vitrectomy with scleral buckling, retinal reattachment, and foreign body removal.

The QuickSet TKP™ is a sterile, single-use, temporary keratoprosthesis intended to replace the pathologic host cornea during surgery to facilitate posterior segment visualization during vitreoretinal surgery and allow intraocular pressure (IOP) to be maintained. Once the posterior segment procedure is completed, the QuickSet TKP™ is removed and penetrating keratoplasty or other appropriate corneal management may be performed.

The QuickSet TKP™ is manufactured from clinical quality polymethyl methacrylate (PMMA) with a proprietary ultraviolet absorber. The device incorporates a transparent optical element and peripheral features that allow fixation using horizontal mattress sutures placed into corresponding device grooves. The design is intended to provide optical clarity, mechanical stability, ease of insertion and removal, a watertight temporary seal, and posterior segment visualization during the intended intraoperative use.

Material and physical properties include PMMA with proprietary UV absorber, refractive index of 1.49, light transmittance greater than 90%, tensile strength of 73, flexural strength of 118, and Rockwell hardness of 105.

Indications for Use

The QuickSet Temporary Keratoprosthesis (QuickSet TKP™) is a surgical aid to provide a transparent optical pathway that permits closed pars plana vitrectomy in eyes with abnormal corneas.

Comparison of Technological Characteristics

Table 1: Substantial Equivalence

Product Characteristic	Landers Wide Field TKP (K910828)	QuickSet TKP™ (K261312)	Comparison / Rationale
Indications for Use	Transparent optical pathway that permits closed pars plana vitrectomy in eyes with abnormal corneas.	The QuickSet Temporary Keratoprosthesis (QuickSet TKP™) is a surgical aid to provide a transparent optical pathway that permits closed pars plana vitrectomy in eyes with abnormal corneas.	Same intended use and similar indications; supported by simulated use.
Material	PMMA	PMMA	Same ophthalmic material family.
Refractive Index	1.49	1.49	Same.
Optical Function	Transparent optical pathway for posterior segment visualization.	Transparent optical pathway for posterior segment visualization.	Similar; supported by optical testing.
Collar Diameter	15.5 mm	12.0 mm	Different; supported by design and testing.
Optical Cylinder Diameter	8.2 mm / 6.2 mm	8.0 mm	Similar.
Optical Cylinder Thickness	1.0 mm	0.82 mm	Similar; supported by dimensional and optical testing.
Attachment Mechanism	6 holes for limbal sutures	4 grooves for horizontal mattress sutures	Different; simulated use demonstrated securement and watertight sealing.
Use	Multiple use	Single use	Different; single-use sterile presentation reduces reprocessing-related risks.
Sterilization	Non-sterile	Ethylene oxide sterilized	Different; EO validation and EO residuals support sterile single-use presentation.
Packaging	Medical pouch	Tyvek/Mylar pouch and box configuration	Different; sterile barrier, distribution, and aging testing support packaging integrity.

Performance Testing - Nonclinical Tests

The following nonclinical performance testing and assessments were conducted for the QuickSet TKP™ to support substantial equivalence to the identified predicate device. The testing evaluated biological safety, sterilization, residuals, microbial cleanliness, endotoxin, packaging and sterile barrier integrity, shelf-life, dimensional and visual characteristics, optical performance, and simulated use sealing and visualization performance. The results support the claimed performance characteristics of the QuickSet TKP™ as a sterile, single-use temporary surgical aid that provides a transparent optical pathway and maintains a watertight seal during representative vitreoretinal surgical use.

Test / Assessment	Purpose	Summary of Results and Support for Substantial Equivalence
Biocompatibility evaluation and testing	Evaluate biological safety for intended temporary ophthalmic surgical use.	ISO 10993-1 evaluation included cytotoxicity, sensitization, and ocular irritation. Cytotoxicity testing resulted in Grade 0 responses at 24 and 48 hours and the device was non-cytotoxic. Sensitization testing found the device was not a contact skin sensitizer. Primary eye irritation testing found no ocular irritation and classified the device as a non-irritant.

Test / Assessment	Purpose	Summary of Results and Support for Substantial Equivalence
Ethylene oxide sterilization validation	Validate EO sterilization for sterile, single-use presentation.	EO sterilization validation was performed in accordance with ISO 11135 and supports the sterile, single-use presentation of the finished device.
Ethylene oxide residuals testing	Confirm residual EO and related residuals are within applicable limits.	EO residuals testing was performed in accordance with ISO 10993-7. Results supported that residual sterilant levels were within applicable limits for the device and intended patient contact.
Bioburden testing	Characterize and control pre-sterilization microbial load.	Bioburden testing was performed in accordance with ISO 11737-1 and USP <61>. Results supported the manufacturing and sterilization controls for the finished device.
Bacterial endotoxins testing	Confirm acceptable endotoxin levels for ophthalmic surgical use.	Bacterial endotoxins testing was performed in accordance with ANSI/AAMI ST72 and USP <85>. Results met the applicable acceptance criterion for the finished sterile device.
Packaging and sterile barrier integrity testing	Verify package integrity after sterilization, handling, transport simulation, and aging.	Packaging validation included environmental conditioning and distribution simulation, visual inspection, bubble leak testing, and seal strength testing using ASTM D4332, ASTM D4169, ASTM F1886/F1886M, ASTM F2096, ASTM F88/F88M, and ASTM F1980, as applicable. The Tyvek/Mylar pouch met predefined sterile barrier acceptance criteria.
Shelf-life / aging support	Support maintenance of package integrity and device performance through labeled shelf life.	Accelerated and real-time aging supported package integrity and continued conformance to critical performance expectations through the claimed shelf life. One-year and two-year aging reports concluded that tested samples met requirements for visual inspection, bubble leak testing, and seal strength testing.
Dimensional and visual inspection	Verify conformance to critical dimensions and workmanship requirements.	Dimensional and visual inspection confirmed conformance to critical device specifications, including optical geometry and absence of burrs, cracks, sharp edges, and visually significant defects.
Optical performance testing	Verify optical characteristics needed for posterior segment visualization.	Optical testing evaluated higher-order aberration, spherical equivalent power (SEP), optical diameter, MTF at 50 lp/mm, and sagittal/thickness using 30 returned samples with repeated measurements. Results supported design targets: low HOA, mean SEP approximately +30.0 D, optical diameter approximately 7.60 mm, MTF at 50 lp/mm greater than 0.40, and sagittal/thickness approximately 2.23 mm. Finished device inspection and rejection controls prevent release of nonconforming units.
Simulated use sealing and visualization validation	Evaluate placement, securement, pressure sealing, and posterior segment visualization under representative surgical conditions.	Simulated clinical wet lab use demonstrated successful device placement and suture engagement, watertight sealing after securement, no leakage during pressurization from 35 mmHg to 120 mmHg, and excellent visualization during representative complex vitreoretinal maneuvers. Additional details are provided below.

Simulated Use / Sealing and Visualization Validation

Simulated use testing was performed in a clinical wet lab by qualified ophthalmologists trained and experienced in the use of TKPs. The procedure included vitrectomy trocar placement, limbal marking, pre-placement of two 7-0 vicryl horizontal mattress sutures, 8 mm corneal trephination, removal of the central corneal button, placement of the QuickSet TKP™, suture engagement into the device grooves, and securement of the device.

After the second suture was tied, the globe was secure and the QuickSet TKP™ was watertight. The eye was pressurized using an Alcon Constellation system from 35 mmHg to 120 mmHg in 10 mmHg increments, and no TKP wound leak was observed throughout the tested pressure range.

Visualization was excellent under representative challenging conditions and remained excellent after additional simulated complex maneuvers, including complete vitrectomy, induction of retinal detachment, peripheral retinectomy, crystalline lens manipulation, and extensive scleral depression. These results support the claimed performance characteristics of maintaining intraocular pressure without leakage and providing posterior segment visualization during representative vitreoretinal surgical maneuvers.

Clinical Performance Testing

Clinical performance testing was not required to support substantial equivalence. The determination of substantial equivalence is based on comparison to the predicate device, similarities in intended use and technological characteristics, risk-based assessments, and the results of nonclinical performance testing.

Substantial Equivalence Discussion

The QuickSet TKP™ and the predicate device have the same intended use and similar indications for use: both provide a transparent optical pathway to permit closed pars plana vitrectomy in eyes with abnormal corneas. Both devices are temporary ophthalmic surgical aids made from PMMA and are intended to facilitate posterior segment visualization during combined corneal and vitreoretinal surgery.

The QuickSet TKP™ differs from the predicate in certain technological characteristics, including dimensions, attachment mechanism, single-use sterile presentation, EO sterilization, and packaging configuration. The differences are addressed by nonclinical testing and risk-based assessments, including simulated use testing demonstrating secure placement and watertight sealing under simulated intraocular pressure conditions, optical testing demonstrating that the device provides an adequate transparent optical pathway, biocompatibility testing demonstrating biological acceptability, and sterilization/packaging testing supporting sterile single-use presentation.

Conclusion

EyeKon Medical, Inc. considers the QuickSet TKP™ to be substantially equivalent to the predicate Landers Wide Field Temporary Keratoprosthesis cleared under K910828. This conclusion is based on the same intended use, similar indications for use, comparable PMMA material and optical function, and supporting nonclinical performance data. The nonclinical test results demonstrate that the QuickSet TKP™ meets its predefined acceptance criteria and support the claimed performance characteristics of providing a transparent optical pathway, maintaining intraocular pressure during simulated use without leakage, and being provided sterile for single use. Therefore, the QuickSet TKP™ nonclinical test results demonstrate substantial equivalence to the predicate device.