February 2, 2022

CorneaGen, Inc
℅ Omid Kodai
President
Khodai Consulting, Inc.
23 Bellflower
Lake Forest, California 92630

Re: K203586
Trade/Device Name: EndoSerter®-PL
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserved
Product Code: OTZ
Dated: December 22, 2021
Received: December 27, 2021

Dear Omid Kodai:

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,

Anjana Jain, PhD
Acting 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)*
K203586

Device Name
EndoSerter®-PL

Indications for Use *(Describe)*

The EndoSerter®-PL is used to insert corneal endothelial allograft tissue measuring less than or equal to 8.0 mm in diameter and 100 microns in central thickness into the anterior chamber through a minimum 4.0 mm incision during endothelial keratoplasty procedures and for loading and storage of donor tissue during transport to the surgeon by trained eye bank technicians, and for storage of donor tissue for up to a maximum of 48 hours.

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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510(k) Summary

I. SUBMITTER

CorneaGen, Inc.
101 N Chestnut St Suite 303
Winston Salem NC 27101
Phone: 336-516-9600
Contact Person: Thomas Miller
Date Prepared: February 1, 2022

II. DEVICE

Name of Device:	EndoSerter®-PL
Common Name:	Graft Insertion Device
Classification Name:	Graft Insertion Instrument for Endothelial Keratoplasty (21 CFR 886.4300)
Regulatory Class:	1, Reserved
Product Code:	OTZ

III. PREDICATE DEVICE

Predicate Device:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Clearance Date
K121579	EK Delivery Device	TDAK Medical Inc.	October 3, 2012

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

Reference Device:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Clearance Date
K090626	EndoSerter®	CorneaGen	January 21, 2011

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

IV. DEVICE DESCRIPTION

Endothelial keratoplasty (EK), also referred to as posterior lamellar keratoplasty, is a form of corneal transplantation during which the diseased inner layer of the cornea, the endothelium, is replaced with healthy donor tissue. Diseases that affect the endothelial layer include Fuchs' endothelial dystrophy, aphakic and pseudophakic bullous keratopathy (corneal edema following cataract extraction), and failure or rejection of a previous corneal transplant.

The EndoSerter®-PL is a sterile, single use, handheld, manual ophthalmic surgical instrument. It is used to preload a processed donor corneal endothelial allograft for storage and transportation to the ophthalmic surgeon and to deliver the allograft into the anterior chamber of the eye during corneal surgery. It is designed to deliver a corneal endothelial allograft into the eye during corneal endothelial keratoplasty. The loading and storage of donor tissue for transport to the surgeon is performed by trained technician at the eye bank. Users of this graft insertion instrument for EK are trained ophthalmic surgeons in a healthcare facility or hospital.

V. INDICATIONS FOR USE

The indications for use statement for the EndoSerter®-PL by CorneaGen is:

> *The EndoSerter®-PL is used to insert corneal endothelial allograft tissue measuring less than or equal to 8.0 mm in diameter and 100 microns in central thickness into the anterior chamber through a minimum 4 mm incision during endothelial keratoplasty procedures and for loading and storage of donor tissue during transport to the surgeon by trained eye bank technicians, and for storage of donor tissue for up to a maximum of 48 hours.*

The Indications for Use statement for the EndoSerter®-PL is not identical to the predicate or reference devices; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and/or effectiveness of the device relative to the predicate or reference devices. The subject, predicate, and reference devices have the same intended use for the insertion of corneal endothelial allograft tissue during endothelial keratoplasty procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Graft Insertion for Endothelial Keratoplasty (EK) is the technological principle for both the subject and predicate as well as the reference devices. It is based on the use of insertion instrumentation for corneal tissue graft EK procedures.

At a high level, the subject and predicate devices and when appropriate the reference device are based on the following same technological elements:

- Same mode of operation in the insertion of corneal endothelial graft for patients requiring Endothelial Keratoplasty (EK)
- Used for loading and storage of donor tissue during transport
- Delivers a circular endothelial tissue button in a rolled configuration
- Provided as a sterile, single use, disposable device
- Loaded by trained technicians at the eye bank
- Donor posterior lamellar endothelial graft of central corneal thickness of 100 microns

The following technological differences exist between the subject and predicate devices:

- Minimum 4 mm incision for the subjective device and 5.1 mm or larger incision for the predicate device. However, the subject device and the reference device are the same in terms of incision size of minimum 4 mm incision.
- Insertion of corneal endothelial allograft tissue measuring less than or equal to 8.0 mm and the predicate and reference device requiring the insertion of donor tissue diameter of less than or equal to 8.5 mm. This difference of 0.50 mm graft size is negligible and does not introduce any potential impact to safety and/or effectiveness.
- Subject device is manufactured using polycarbonate, isoplast, polyimide, stainless steel, silicone, acrylonitrile butadiene styrene (ABS), white, blue, and black colorant. Manufacturing materials for the predicate device is not commercially available or available in public records. The reference device is manufactured using polycarbonate, isoplast, polyimide, stainless steel, white, blue, and black colorant. The addition of silicone and ABS does not introduce any

impact to safety and/or effectiveness based upon biocompatibility testing performed in accordance with ISO 10993-1.

- Subjective device has tissue storage capability up to 48 hours and the predicate device has tissue storage capability up to 72 hours. This difference does not introduce any potential impact to the safety and/or effectiveness of the subject device in delivering the allograft, and relevant testing has confirmed the stability of the subjective device during tissue handling and stability testing.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the EndoSerter®-PL device was conducted in accordance with the FDA Guidance issued on September 4, 2020 “Use of International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process”.” The battery of testing included the following tests which demonstrated biocompatibility of the device with direct contact to the human tissue:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Pyrogenicity

The EndoSerter®-PL device is considered tissue contacting for a duration of less than 24 hours, while the allograft tissue is considered a permanent implant.

Tissue Handling and Stability Testing

The purpose of this study was to quantitatively determine the endothelial cell damage (endothelial cell loss) when using the EndoSerter®-PL to load, store, transport, and deliver donor allograft tissue. The test results demonstrated that the device did not have any leaking, damage, or shifting of the tissue grafts during the transportation and storage.

Sterilization Validation

The purpose of this study was to adopt, by equivalency, the EndoSerter®-PL into the existing radiation sterilization process used for the EndoSerter®. The radiation sterilization dose range provided a Sterility Assurance Level (SAL) of 10^{-6} in accordance with FDA Guidance issued on January 21, 2016 "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Shelf Life and Transportation Testing

The purpose of this study was to perform leak test to demonstrate that the EndoSerter®-PL does not leak corneal storage media during storage and transportation over a 48-hour period prior to and after accelerated aging. The results of this leak test validated that storage media did not leak from the EndoSerter®-PL during storage and transportation over a 48-hour period prior to and after accelerated aging.

Aseptic Handling Testing

This testing, performed in accordance with the USP<71>, Method Suitability Test procedures, was conducted to demonstrate the ability to maintain aseptic handling of tissue without increased risk of contamination on transfer to and storage in the EndoSerter®-PL. The testing results demonstrated that the aseptic handling utilized by CorneaGen to load and transport cornea tissue in the EndoSerter®-PL did not increase the risk of contamination of the tissue.

Dimensional, Functional, and Mechanical Testing

The purpose of this study was to perform dimensional, functional, and mechanical testing utilizing measurement of critical dimensions including additional dimensions relating to mating components, visual inspection, and fit of those components. The study confirmed that the EndoSerter®-PL components perform mechanically and functionally as designed. Therefore, supporting the acceptable use of the device components and materials required in the design and assembly of the EndoSerter®-PL.

VIII. CONCLUSION

The EndoSerter®-PL, the subject device, is substantially equivalent to both the predicate and the reference devices' intended use which includes:

- same mode of operation in the insertion of corneal endothelial graft for patients requiring Endothelial Keratoplasty (EK)

- used for loading and storage of donor tissue during transport
- delivering a circular endothelial tissue button in a rolled configuration
- provided as a sterile, single use, disposable device
- loaded by trained technicians at the eye bank
- posterior lamellar endothelial graft of central corneal thickness of 100 microns corneal thickness, as well as the duration of time that tissue can be stored within the device.

The minimal technological differences of EndoSerter®-PL, the subject device, to the predicate and the reference devices, do not pose any potential impact to safety and/or effectiveness as demonstrated by the performance testing conducted.