

OCT 3 2012

510(k) Summary**TDAK Medical, Inc.****11575 Sorrento Valley Road****Suite 214****San Diego, CA 92121****SUMMARY**

Submitter's name: TDAK Medical Inc.
11575 Sorrento Valley Road
Suite 214
San Diego, CA 92121

Name of contact person: Greg Holland
Regulatory Specialists, Inc.
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Date the summary was revised: September 12, 2012

Name of the device: EK Delivery Device
Trade or proprietary name: EK Delivery Device
Common or usual name: Endothelial Keratoplasty (EK) Injector
Classification Panel: Ophthalmic

Product Code	Classification Regulation	Classification Name
OTZ	886.4300	Lens, Guide, Intraocular

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K090626	EndoSerter™	Ocular Systems, Inc.

The Endothelial Keratoplasty Injector is a single-use, disposable device that allows an ophthalmic surgeon to insert a previously prepared disc of posterior donor cornea into the eye of a recipient patient through a small incision during a posterior corneal transplant surgical procedure. The function of the device is to insert the flat disc of donor corneal tissue within a cylindrical tube that is sized to fit into 5.1 mm or larger corneal or scleral incision, and to pull or push this donor corneal tissue into the anterior chamber of the eye as part of an Endothelial Keratoplasty procedure. This device was designed to insert donor posterior corneal tissue ≤ 8.5 mm in diameter, 100 μ m to 220 μ m in thickness, through a 5.1 mm or larger corneal incision.

Indications:

The EK Delivery Device is to be used by ophthalmic surgeons trained in Endothelial Keratoplasty (EK) procedures and trained in the use of the EK Delivery Device as:

- An aid facilitating the insertion of donor corneal posterior lamellar endothelial graft of 100 – 220 μ m into the anterior chamber of the eye during endothelial keratoplasty.
- For use in a 5.1 mm or larger incision and a maximum donor tissue diameter of ≤ 8.5 mm).
- 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 72 hours.

Comparison to Predicate:

The EK Delivery Device is similar to its predicate in basic functionality of inserting corneal tissue during endothelial keratoplasty (EK) procedure. Both are intended to be an aid to delivering the corneal tissue in a convenient form for the ophthalmic physician.

The EK Delivery Device is to be used by ophthalmic surgeons trained in Endothelial Keratoplasty (EK) procedures and trained in the use of the EK Delivery Device as:

- An aid facilitating the insertion of donor posterior lamellar endothelial graft of 100 μ m to 220 μ m in thickness into the anterior chamber of the eye during endothelial keratoplasty.
- 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 72 hours.

Product Name	<u>Proposed:</u> EK Delivery Device	<u>Predicate:</u> K090626 EndoSerter™
Indications for Use	<p>The EK Delivery Device is to be used by ophthalmic surgeons trained in Endothelial Keratoplasty (EK) procedures and trained in the use of the EK Delivery Device as:</p> <ul style="list-style-type: none"> • An aid facilitating the insertion of donor posterior lamellar endothelial graft of 100µm to 220µm in thickness into the anterior chamber of the eye during endothelial keratoplasty. • For use in a 5.1 mm or larger incision and a maximum donor tissue diameter of ≤ 8.5 mm). • 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 72 hours. 	<p>The EndoSerter™ is used to insert corneal endothelial allograft tissue measuring less than or equal to 8.5mm in diameter and 175 micron in central thickness into the anterior chamber through a minimum 4mm incision during endothelial keratoplasty procedures</p>
Product Code	OTZ	OTZ
Regulation Number	886.4300	886.4300
Class	1, reserved	1, reserved
Review Advisory Committee	Ophthalmic	Ophthalmic
Target Population	Patients requiring Endothelial Keratoplasty	Patients requiring Endothelial Keratoplasty
Anatomical Site	Eye	Eye

Product Name	<u>Proposed:</u> EK Delivery Device	<u>Predicate:</u> K090626 EndoSerter™
Design	The EK Delivery device consists of four components: (1) the Trocar which is used to hold the graft material and introduce it into the anterior chamber of the recipient eye, (2) the Trocar Holder, which is used to close the proximal end of the Trocar and as an ergonomic handle to aid the surgeon handling the device, (3) the Injector Assembly, which is a plunger to push the endothelial keratoplasty tissue out of the Trocar and into the anterior chamber of the recipient eye, and (4) End Plug used during shipping.	The EndoSerter® consists of the instrument's body and its internal mechanism and carrier. The EndoSerter® is a sterile, disposable, single use only device.
	Delivers a circular endothelial tissue button in a rolled configuration.	Delivers a circular endothelial tissue button in a rolled configuration.
Sterility	Sterile Radiation	Sterile Radiation
Storage Capability	Yes 72 hours	No

Testing has been completed showing the following:

- Sterilization Validation
- Shelf Life
- Mechanical Strength
- Tissue Handling and Stability
- Biocompatibility

This testing shows that the predicate and TDAK device are equivalent and pose no new safety issues.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

TDAK Medical, Inc.
c/o Mr. Greg Holland
Regulatory Specialist, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

OCT 3 2012

Re: K121579

Trade/Device Name: EK Delivery Device
Regulation Number: 21 CFR 886.4300
Regulation Name: Graft Insertion Instrument for Endothelial Keratoplasty
Regulatory Class: Class I (reserved)
Product Code: OTZ
Dated: September 12, 2012
Received: September 13, 2012

Dear Mr. Holland:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement
Indications for Use

510(k) Number (if known): K121579

Device Name: EK Delivery Device

Indications for Use:

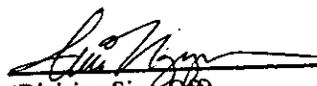
The EK Delivery Device is to be used by ophthalmic surgeons trained in Endothelial Keratoplasty (EK) procedures and trained in the use of the EK Delivery Device as:

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- For use in a 5.1 mm or larger incision and a maximum donor tissue diameter of ≤ 8.5 mm)
- 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 72 hours.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121579

Page 1 of 1
