January 30, 2019

Massachusetts Eye and Ear Infirmary d/b/a Boston
% Ms. Kristy Katzenmeyer-Pleuss
Senior Medical Research Manager, Regulatory
NAMSA Clinical & Consulting Services, GmbH
Industrie Center Obernburg
63784 Obernburg am Main
Germany

Re: K182986
Trade/Device Name: Boston Keratoprosthesis, Type I Lucia
Regulation Number: 21 CFR 886.3400
Regulation Name: Keratoprosthesis
Regulatory Class: Class II
Product Code: HQM
Dated: December 26, 2018
Received: December 31, 2018

Dear Ms. Kristy Katzenmeyer-Pleuss:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Jennifer N. Brown -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Boston Keratoprosthesis, Type I Lucia (Boston KPro)

Indications for Use *(Describe)*
The Boston KPro is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.

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.

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510(k) Summary

(*per 21 CFR 807.92)*

Submitter:	Massachusetts Eye and Ear Infirmary, d/b/a Boston Keratoprosthesis 243 Charles Street Boston, MA 02114 USA Contact Person: Larisa Gelfand Position: Director Boston KPro Business Operations Telephone: (617) 573-4463
Consultant/Contact Person:	NAMSA Clinical & Consulting Services GmbH Industrie Center Obernburg 63784 Obernburg am Main Germany Primary Contact: Dr. Kristy Katzenmeyer-Pleuss, PhD Position: Senior Medical Research Manager, Regulatory Telephone: +49 151 7411 2739
Date Prepared:	October 19, 2018
Trade Name:	Boston Keratoprosthesis (Boston KPro), Type I Lucia
Common/Usual Name:	Keratoprosthesis
Classification:	Classification Name: Keratoprosthesis, Permanent Implant Class: II (Special Controls) Regulation Number: 21 CFR 886.3400
Product Code:	HQM
Predicate Device:	Boston Keratoprosthesis (Boston KPro), Type I (Click-on design) K121203 Cleared on May 10, 2013
Device Description:	The subject of this Special 510(k) is a modification of the Boston KPro, Type I (Click-on design) keratoprosthesis permanent implant device that was previously cleared under K121203. The modified device (subject device) will be called Boston KPro, Type I Lucia.

	The Boston KPro, Type I Lucia is an artificial corneal device that can be used in patients with severe corneal opacity. The Boston KPro, Type I Lucia is used after standard corneal transplant has failed or when such a transplant would be unlikely to succeed. Thus, keratoprosthesis implantation is a procedure designed to help patients whose conditions are the most difficult to treat. The Boston KPro, Type I Lucia is implanted through and fixed only to the cornea and is used for corneal blindness when the eyelids, blink mechanism, and tear film are intact. The device consists of two components: • a front plate constructed of clear polymethyl methacrylate (PMMA) plastic, and • a back plate constructed of titanium that locks the device in place around a corneal donor graft. The Boston KPro, Type I Lucia is supplied with an assembly tool/pin to assist in device assembly.
Intended Use:	The Boston KPro is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.
Substantial Equivalence:	This Special 510(k) seeks to modify the titanium back plate manufacturing method from machining of titanium rod stock to photoetching and forming/bending of thin titanium sheets. The titanium raw material type and specification is unchanged from the predicate. Several additional small changes are also being made to the back plate, including a change in the shape of the circular holes to ovaloids, a change in diameter, and removal of a slit. Aside from the new photoetching and forming/bending processes, the other manufacturing processes for the back plate, including the sandblasting and cleaning process performed after the photoetching and forming/bending, remain unchanged from the predicate device. In order to accommodate the modified back plate, several small changes are also being made to the dimensions of the front plate component and assembly tool. However, the PMMA front plate and assembly tool manufacturing processes remain unchanged from the predicate device.

There is no change in intended use, indications for use, patient population, fundamental scientific technology, principles of operation, raw materials, packaging, sterilization, shelf life, device performance specifications, or manufacturing inspection/monitoring criteria between the predicate and subject devices.

No changes are being made to the Type II keratoprosthesis implant device cleared under K121203.

A substantial equivalence comparison between the predicate Boston KPro, Type 1 (Click-on design) device cleared under K121203 and the subject Boston KPro, Type I Lucia device is shown in the table below.

Product Characteristics	Boston KPro, Type I (Click-on design) (predicate; K121203)	Boston KPro, Type I Lucia (subject device)
Intended Use	The Boston Keratoprosthesis is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.	Same
Back Plate Material	Titanium Type: 6Al-4V Grade: ELI Specification: Grade 23 Conforms to ASTM F136	Same
Black Plate Material Physical Form and Manufacturing	Titanium rod stock cut by machining on a lathe	Thin titanium sheet is now photoetched and formed/bent • Photoetching is subcontracted to Tecomet, Inc. (Wilmington, MA) • Forming/bending performed at MEEI facility
Back Plate Dimensions	8.5 mm diameter	7.8 mm diameter • Diameter is within range of MEEI's other commercially available devices: o 7.0 mm and 8.5 mm for Boston KPro Snap-on design (K915062);

		○ 8.5 mm for Boston KPro, Type I Click-on design (K121203)
Back Plate Structure	1.2 mm diameter round holes (16 evenly spaced) • Total surface area of 16 round holes is 18.1 mm^2 Has a slit to facilitate assembly	Elongated "ovaloid" slots tapered from 1.01 mm down to 0.53 mm in diameter (16 evenly spaced) • Total surface area of 16 ovaloid slots is 23 mm^2 There is no longer a slit in the back plate
Back Plate Curvature Angle	20.00°	Same
Back Plate Thickness	0.30 mm	Same
Front Plate Material	Polymethylmethacrylate (PMMA)	Same
Front Plate Dimensions: • **Diameter** • **Stem Length**	 5.0 mm 1.7 mm	Same
Front Plate Stem Lead Angle	See drawing of predicate Boston KPro, Type I front plate	The stem lead angle on the front plate has been changed slightly to allow for proper assembly and disassembly of the new back plate; See drawings of Boston KPro, Type I Lucia (subject device) front plate
Front Plate Optical Properties	Aphakic version: • Available in axial lengths of 16.0 mm to 31.00 mm Pseudophakic version: • Axial length measurement not necessary for patients with intraocular lens in place and assumed to target emmetropia	Same
Assembly Tool Design	Assists in assembly of device for implantation.	Assembly tool design has dimensions to fit new back plate and is used for the exact same purpose as predicate
Assembly Tool Material	Delrin (Acetal resin)	Same
Packaging	Wipak/Film Medical Pouch	Same
Sterilization Method	Ethylene Oxide	Same
SAL	10^{-6}	Same
Sterilization Residuals	EO: < 0.5 µg EO/device/day;	Same

	< 1.25 µg EO/device total ECH: < 2 µg ECH/device/day; < 5 µg ECH/device total	
Endotoxin Limits	≤ 0.2 EU/device	Same
Bioburden Limits	Initial Alert Limit: Bioburden ≥28.0 CFUs/device Initial Action Limit: Bioburden ≥119 CFUs/device Note: Bioburden limits apply to each of the following: Aerobic Aerobic spores Anaerobic Fungal	Same
MR Labeling	MR-Conditional	Same
Assembly Force Specifications	< 3 kg force for assembly	< 5 kg force for assembly
Disassembly Force Specifications	> 5.5 kg force for disassembly	Same
Manufacturing Inspection Criteria	100% inspection for dimensions, burrs/cracks, sharp edge, shadow graph visual, actual back focal length in air	Same

Verification and Validation Testing:

The following verification and validation activities were performed to confirm that the modified device meets its functional and performance requirements:

- **EO sterilization validation** per ANSI/AAMI/ISO 11135:2014 and AAMI TIR28:2009/(R2013)
- **EO residuals testing** per AAMI/ANSI/ISO 10993–7: 2008(R)2012
- **Bioburden testing** per ISO 11737-1:2006/Technical Corrigendum 1 2007 and USP <61> (2017)
- **Endotoxin (LAL) testing** per ANSI/AAMI ST72:2011/R2016, USP <85> (2017) and USP <161> (2017)
- **Cytotoxicity testing** per ISO 10993-5:2009 and FDA GLP regulations (21 CFR 58)

	• **MR Safety Testing**
	  • **Magnetic field interactions**: translational attraction/deflection angle per ASTM F2052-15 and torque per ASTM F2213-06 (R2011)
	  • **MRI-related heating** per ASTM F2182-11a
	  • **Image Artifacts** per ASTM F2119-07 (R2013)
	• **Device assembly force testing**
	• **Device disassembly force testing**
	
	Testing of the Boston KPro, Type I Lucia has demonstrated that the back plate manufacturing change from machining to photoetching and forming/bending as well as other minor changes to the back plate, front plate, and assembly tool do not modify product performance. The product has been found to fulfill prospectively defined performance criteria and that the modified device meets user needs.
	
	No preclinical animal or clinical testing was performed to establish substantial equivalence to the predicate.

Conclusion:	MEEI considers the modified device (Boston KPro, Type I Lucia) to be substantially equivalent to the predicate Boston KPro, Type I (Click-on device) cleared under K121203. This conclusion is based upon the devices' similarities in technological characteristics, performance specifications, raw materials, and indications for use. As mentioned above, there are only minor differences between the subject and predicate devices. Non-clinical testing performed confirms that these minor differences do not affect the device's safety or effectiveness as the modified device meets the same functional and safety requirements as the predicate. Therefore, the two devices can be considered substantially equivalent. In conclusion, the subject device (Boston KPro, Type I Lucia) described in this application can be considered substantially equivalent to the predicate device [Boston KPro, Type I (Click-on) model] cleared under K121203.