December 15, 2017

AST Products, Inc.
William Lee, Ph.D.
R&D and Regulatory Affairs
9 Linnell Circle
Billerica, MA 01821

Re: K172228
Trade/Device Name: pioli™ IOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: November 2, 2017
Received: November 6, 2017

Dear William Lee, Ph.D.:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Denise L. Hampton -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)*
K172228

Device Name
pioli™ IOL Delivery System

Indications for Use *(Describe)*
The pioli™ IOL Delivery System is a single-use, sterile device intended to insert a single-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation through an incision. The pioli™ IOL Delivery System is only for the insertion of the Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the IOL approved labeling.

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.

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July 20, 2017

510(k) Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.92, 510(k) summary is provided.

1. Submitter

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2. Official Correspondence/Contact Person

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3. 510(k) Preparer

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4. Product Name

- Trade Name: pioli™ IOL Delivery System
- Common Name: Folders and Injectors, Intraocular Lens (IOL)

5. Device Classification

- Classification Name: Class I (21 CFR § 886.4300 Intraocular lens guide)
- Classification Panel: Ophthalmic (86)
- Product Code: MSS

6. Legally Marketed Predicates

- K142056: lioli™ IOL Delivery System (Models: LIOLI-18, LIOLI-22, LIOLI-24)

7. Device Description

The pioli™ IOL Delivery System is a single-use, sterile device intended to insert a single-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation

through an incision. The pioli™ IOL Delivery System is only for the insertion of the Lenstec Softec I IOL and IOL models validated for use with this device as indicated on the IOL approved labeling.

The set consists of a single-use, sterile syringe injector with a silicone tip and a single-use, sterile LubriMATRIX™-treated cartridge.

The tip of the plunger, housed in the injector, is covered by a silicone cushion that provides a good contact to the lens to ensure a smooth delivery. The plunger is advanced by applying a direct forward motion.

Note: LubriMATRIX™ is a proprietary treatment composed of a hydrophilic polymer and a lubricious polymer engrafted onto the surface of the cartridge via a chemical polymerization process. Refer to MAF-1963 for further information.

8. Intended Use and Indications for Use

The pioli™ IOL Delivery System is a single-use, sterile device intended to insert a single-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation through an incision. The pioli™ IOL Delivery System is only for the insertion of the Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the IOL approved labeling.

The pioli™ IOL Delivery System shares the same intended use and indications for use for lens insertion into the eye with the predicate device referenced in this 510(k) premarket notification application. Refer to **Table 1**.

Table 1. *Device Comparisons – Intended Use and Indications for Use*

Trade Name	Manufacturer	Regulation No.	Product Code	Regulation Description	510(k) No.	Intended Use & Indications for Use
pioli™ IOL Delivery System	AST Products, Inc.	886.4300	MSS	Intraocular Lens Guide	New device	The pioli™ IOL Delivery System is a single-use, sterile device intended to insert a one-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation through an incision. The pioli™ IOL Delivery System is only for the insertion of Lenstec Softec I IOL and IOL models validated for use with this device as indicated on the IOL approved labeling.
lioli™ IOL Delivery System	AST Products, Inc.	886.4300	MSS	Intraocular Lens Guide	K142056	The lioli™ IOL Delivery System is a single-use, sterile device intended to insert a one-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation through an incision. Only for the insertion of IOL models validated for use with this device as indicated in the IOL approved labeling.

9. Technological Characteristics

The pioli™ IOL Delivery System is an intraocular lens delivery system used for progressive folding and delivering intraocular lenses into the eye for replacement of the human crystalline lens. The device consists of:

(1) a lubricious coated cartridge structure in preparation for intraocular lens loading and lens folding
(2) a single-use injector with a silicone-tipped plunger used to advance the lens into the capsular bag.

The pioli™ IOL Delivery System is intended for use during cataract surgery.

An intraocular lens folded into the cartridge reduces the surgical incision size.

The pioli™ IOL Delivery System shares many similar technological characteristics for lens insertion into the eye with the predicate device referenced in this 510(k) premarket notification application. Refer to **Tables 2 and 3**.

Table 2. *Device Comparisons – Technological Characteristics*

Trade Name	Design	Operating Principle	Forward Motion Principle	Biocomp.	Sterilization Method	Setting Used	Patient Contact	Recommended for Use With	Human Factors	Performance Criteria Met?
pioli™ IOL Delivery System	A sterile, single use disposable device	The cartridge is back loaded into the injection system and the IOL is pushed through the cartridge into the eye	Plunger/ Syringe type	Yes	ETO sterilization SAL level $1x10^{-6}$	Hospital/ Surgery center	Distal end of cartridge to place lens in eye	FDA-approved viscoelastic	For use by doctors only	Yes
lioli™ IOL Delivery System	A sterile, single use disposable device	The cartridge is loaded into the injection system and the IOL is pushed through the cartridge into the eye	Plunger/ Syringe type	Yes	ETO sterilization SAL level $1x10^{-6}$	Hospital/ Surgery center	Distal end of cartridge to place lens in eye	FDA-approved viscoelastic	For use by doctors only	Yes

Table 3. *Device Comparisons – Materials*

Trade Name	Device Materials	Standards Met
pioli™ IOL Delivery System	Injector – Polycarbonate (144R) Plunger – Polycarbonate (144R) Silicone Tip – Silicone (R 401) Cartridge – Polypropylene (HD850MO) Spring – Stainless Steel (SS304)	ISO 11979-3:2012 ISO10993-5: 2009 ISO 10993-10: 2010
lioli™ IOL Delivery System	Injector – Polycarbonate (144R) Plunger – ABS Silicone Tip – Silicone (R 401) Cartridge – Polypropylene (HD850MO) Spring – Stainless Steel (SS304)	ISO 11979-3:2012 ISO10993-5: 2009 ISO 10993-10: 2010

10. Performance Data (Nonclinical and/or Clinical)

— Non-clinical Tests:

All lenses were delivered through the pioli™ according to the loading and delivery procedure in the Indications for Use (IFU).

The IOLs were evaluated for the optical properties, sagitta, and overall surface and bulk homogeneity before and after being surgically manipulated using the pioli™ IOL Delivery System, as well as lens opening time after folding. The pioli™ IOL Delivery System was also evaluated for its cartridge performance, such as overall cartridge surface and bulk homogeneity.

IOL optical properties and overall surface and bulk homogeneity inspection were conducted in accordance with ISO 11979-2, Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods and ISO 11979-3, Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods.

After delivery, all lenses were observed for possible damages or scratches using a microscope. All delivered lenses showed no damages or scratches, and were within dimensional specifications. Also, all cartridges showed no damages after lens delivery.

The resulting data from simulated surgical manipulation of pioli™ IOL Delivery System to deliver intraocular lenses (IOLs) showed that pioli™ IOL Delivery System (Model: PIOLI-D) can successfully deliver Lenstec's hydrophilic Softec 1 IOLs of low to high diopters and IOL models validated for use with this device as indicated on the IOL approved labeling without affecting the functionality of the lens.

The components of pioli™ IOL Delivery System that have direct and indirect contact with the patient are manufactured of the same materials and same manufacturing processes as the predicate device, lioli™ IOL Delivery System.

Since the same materials and the same manufacturing processes have been used for components that have direct and indirect contact with the patient in both medical devices, we therefore conclude that the biocompatibility testing on particularly the cartridge and the silicone tip of the predicate device are applicable to the subject device.

The resulting data from packaging validation showed that the most suitable parameter to seal the packaging of pioli™ IOL Delivery System was under the condition of 129°C, 3.6 seconds, with all blisters passing the appearance inspection, peeling strength and adhesion tests.

— Clinical Tests: Not required for this device.

11. Conclusion

The pioli™ IOL Delivery System shares the same intended use and indications for use, and technological characteristics for lens insertion into the eye with the predicate device referenced in this 510(k) premarket notification application.

Based on the assessment of these findings, along with the results of Biocompatibility, Sterilization and Shelf-Life testing, the pioli™ IOL Delivery System is substantially equivalent to the referenced legally marketed predicate device provided in this 510(k) premarket notification submission.