



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

April 9, 2015

AST Products, Inc.
% David Lim, Ph.D.
Regulatory Consultant
3955 Riner Road, Box 148
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Re: K142056
Trade/Device Name: lioli™ IOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: March 4, 2015
Received: March 6, 2015

Dear Dr. Lim:

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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Kesia Y. Alexander -A

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

Indications for Use

510(k) Number (if known)
K142056

Device Name
Ioli™ IOL Delivery System

Indications for Use (Describe)

The Ioli™ 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.

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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April 6, 2015

1. 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.

2. Submitter

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5. Product Name

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

6. Device Classification

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

7. Legally Marketed Predicate

K103495: ASICO SofTip Injector System, AS-9300

8. Device Description

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.

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.

9. Intended Use and Indications for Use

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.

The lioli™ 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**.

Note: One of the statutory requirements for demonstrating substantial equivalence (SE) is to show that a new device has the same intended use, which is broader than indications.

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
lioli™ IOL Delivery System	AST Products, Inc.	886.4300	MSS	Intraocular Lens Guide	New device	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.
ASICO SofTip Injector System, AS-9300	ASICO LLC	886.4300	MSS	Intraocular Lens Guide	K103495	The ASICO SofTip Injector System is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a human eye. The system provides a tubular pathway through an incision, allowing the delivery of an IOL into the human eye. This is indicated for the insertion only of models of IOL that allow use of this injector in their approved labeling.

10. Technological Characteristics

The lioli™ 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 cartridge that holds the intraocular lens in position in preparation for loading
- (2) and a single-use injector that houses a silicone-tipped plunger used to advance the lens into the capsular bag.

An intraocular lens folded into the cartridge reduces the surgical incision size. Injector tip outer diameter measurements vary in size (1.67mm, 2.00mm and 2.25mm, respectively).

- Model LIOLI-18 is with an injector tip outer diameter of 1.67mm
- Model LIOLI-22 is with an injector tip outer diameter of 2.00mm
- Model LIOLI-24 is with an injector tip outer diameter of 2.25mm

The lioli™ 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.

Differences in design/materials between lioli™ IOL Delivery System and the predicate device are not critical and do not affect its safety and effectiveness when used as labeled as patient contact during lens placement for the listed device is only intended to occur between the human eye and materials in which the both devices share – a single-use, sterile polypropylene cartridge and silicone tip. 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?
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
ASICO SofTip Injector System, AS-9300	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/ Screw 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
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
ASICO SofTip Injector System, AS-9300	Injector – Polycarbonate (144R Blue) Plunger – Polycarbonate (144R White) Silicone Tip – Silicone Cartridge - Polypropylene Spring – Stainless Steel (SS304)	ISO 11979-3:2006 ISO10993-5: 2009 ISO 10993-10: 2002

11. Performance Data (Nonclinical and/or Clinical)

— Non-clinical Tests:

All lenses were delivered through the lioli™ 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 each of the 3 models of lioli™ IOL Delivery System, as well as lens opening time after folding. Each lioli™ IOL Delivery System were 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 lioli™ IOL Delivery System to deliver hydrophilic intraocular lenses (IOL) showed that lioli™ IOL Delivery System models LIOLI-18, LIOLI-22 and LIOLI-24, can successfully deliver Lenstec's Softec 1 IOL of low to high diopters without affecting the functionality of the lens.

To evaluate the safety of the proposed new device, performance testing for all contact materials has been tested for biocompatibility and was found to be safe.

— Clinical Tests: Not required for this device.

12. Conclusion

The lioli™ 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.

Differences in design/materials between lioli™ IOL Delivery System and the predicate device are not critical and do not affect its safety and effectiveness when used as labeled as patient contact during lens placement for the listed device is only intended to occur between the human eye and materials in which both devices share – a single-use, sterile polypropylene cartridge and silicone tip.

The resulting data from simulated surgical manipulation of lioli™ IOL Delivery System to deliver intraocular lenses (IOL) showed that lioli™ IOL Delivery System models LIOLI-18, LIOLI-22 and LIOLI-24 can successfully deliver hydrophilic IOLs of low to high diopters without affecting the functionality of the lens.

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