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

Re: K200057
Trade/Device Name: bioli lOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: April 26, 2020
Received: April 28, 2020

Dear William Lee:

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,

For Tieuvi Nguyen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200057

Device Name
bioli™ IOL Delivery System

Indications for Use *(Describe)*
The bioli™ IOL Delivery System is a single-use, sterile device intended to insert an approved single-piece foldable acrylic intraocular lens (IOL) into the human eye through an incision.

The bioli™ IOL Delivery System is for implantation of qualified Lenstec Softec 1 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.

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May 29, 2020

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

AST Products, Inc.
9 Linnell Circle
Billerica, MA 01821 USA
Tel: (978) 667-4500
Fax: (978) 667-9778

2. Official Correspondence/Contact Person

William Lee, Ph.D.
VP, R&D and Regulatory Affairs
AST Products, Inc.
9 Linnell Circle
Billerica, MA 01821 USA
Tel: (978) 667-4500
Fax: (978) 667-9778
Email: wlee@astp.com

3. 510(k) Preparer

William Lee, Ph.D.
VP, R&D and Regulatory Affairs
AST Products, Inc.
9 Linnell Circle
Billerica, MA 01821 USA
Tel: (978) 667-4500
Fax: (978) 667-9778
Email: wlee@astp.com

4. Product Name

- Trade Name: bioli™ IOL Delivery System (Models: BIOLI-C, BIOLI-rC, BIOLI-D)
- 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

- K182965 BL-Cart™ IOL Delivery Cartridge

7. Device Description

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

The bioli™ IOL Delivery System is composed of two parts:

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

The cartridge incorporates a smooth, internal geometry that progressively folds the lens for delivery through conventional nozzle geometry. A coating is applied to the cartridge including the inner surfaces to increase lubricity.

The cartridge is loaded by positioning the intraocular lens into the cartridge, folding the trailing haptic onto the anterior side of the optic, and finally pushing the optic edge of the lens to position it as far into the cartridge as the forceps will permit. After the cartridge is attached onto the injector, the system is now ready for the advancement of the plunger to deliver the lens.

The bioli™ IOL Delivery System and the referenced legally marketed predicate, BL-Cart™ IOL Delivery Cartridge, share the same principal method to implant an intraocular lens into the eye. Both utilize the same lens folding system design in which IOLs are folded and/or delivered from an injector system and the resulting optical and physical properties of the IOL remain unchanged as a result of folding/delivery.

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. LubriMATRIX™ is applied to AST Products' current line of IOL Delivery Systems: lioli™ IOL Delivery System (K142056), pioli™ IOL Delivery System (K172228), and BL-Cart™ IOL Delivery Cartridge (K182965).

8. Intended Use and Indications for Use

The bioli™ IOL Delivery System is a single-use, sterile device intended to insert an approved single-piece foldable acrylic intraocular lens (IOL) into the human eye through an incision.

The bioli™ IOL Delivery System is only for the insertion of Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the approved IOL labeling.

The bioli™ IOL Delivery System and the referenced legally marketed predicate device share the same principal folding method to implant an intraocular lens into the eye and similar intended use and indications for use for lens insertion into the eye, and thus does

not raise any new questions or concerns regarding safety and effectiveness. 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
bioli™ IOL Delivery System (Models: BIOLI-C, BIOLI-rC, BIOLI-D)	AST Products, Inc.	886.4300	MSS	Intraocular Lens Guide	New device	The bioli™ IOL Delivery System is a single-use, sterile device intended to insert an approved single-piece foldable acrylic intraocular lens (IOL) into the human eye through an incision. The bioli™ IOL Delivery System is only for the insertion of Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the approved IOL labeling.
BL-Cart™ IOL Delivery Cartridge (Model: Type D)	AST Products, Inc.	886.4300	MSS	Intraocular Lens Guide	K182965	The BL-Cart™ IOL Delivery Cartridge is a single-use, sterile device intended to insert an approved single-piece foldable acrylic intraocular lens (IOL) into the human eye through a surgical procedure. The cartridge is intended to be used in conjunction with Alcon Monarch® III IOL Delivery System injector. The BL-Cart™ IOL Delivery Cartridge is only for the insertion of Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the approved IOL labeling.

9. Technological Characteristics

The bioli™ IOL Delivery System is an intraocular lens delivery system used for progressive folding and delivering of an intraocular lens into the eye for replacement of the human crystalline lens during cataract surgery. The device consists of a lubricious coated cartridge and a single-use injector with a silicone-tipped plunger used to advance the lens into the capsular bag.

The bioli™ IOL Delivery System shares 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	Advancement Mechanism	Biocomp.	Sterilization Method	Setting Used	Patient Contact	Recommended for Use With	Human Factors	Performance Criteria Met?
bioli™ IOL Delivery System (Models: BIOLI-C, BIOLI-rC, BIOLI-D)	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
BL-Cart™ IOL Delivery Cartridge (Model: Type D)	A sterile, single-use disposable coated cartridge	The one-piece disposable cartridge is loaded into a reusable handpiece injection system and the IOL is pushed through the cartridge into the eye	Plunger-like, non-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
bioli™ IOL Delivery System (Models: BIOLI-C, BIOLI-rC, BIOLI-D)	Injector Barrel – Polycarbonate (144R) Plunger – ABS (PA-758) Silicone Tip – Silicone (R 401) Cartridge – Polypropylene (RJ880MO-12) Spring – Stainless Steel (SS304)	ISO 11979-3:2012 ISO10993-5: 2009 ISO 10993-10: 2010
BL-Cart™ IOL Delivery Cartridge (Model: Type D)	Cartridge - Polypropylene (RJ880MO-12)	ISO 11979-3:2012 ISO10993-5: 2009 ISO 10993-10: 2010

10. Performance Data (Nonclinical and/or Clinical)

— Non-clinical Tests:

The bioli™ IOL Delivery System contacts the patient's eye directly for a limited (≤24hr) time. The device also has limited contact with the IOL. Based on the contact duration, cytotoxicity, sensitization and ocular irritation tests were performed. In addition, acute systemic toxicity and material-mediated pyrogenicity tests were also performed. The biocompatibility testing was performed in accordance with International Standard Organization (ISO) Biocompatibility evaluation of medical devices- parts 5, 10 and 11. The biocompatibility testing was found acceptable.

All lenses were delivered through the bioli™ IOL Delivery System according to the loading and delivery instructions.

The IOLs were evaluated for optical properties, dimensional properties and overall surface and bulk homogeneity before and after being surgically manipulated using the bioli™ IOL Delivery System, as well as lens opening time after folding. The bioli™ 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 11979-3:2012, Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods.

After delivery, lenses were observed for possible damages or scratches using a 10x microscope and showed passing results, and were within dimensional specifications. The bioli™ IOL Delivery System also showed no damage after lens delivery.

The resulting data from simulated surgical manipulation of bioli™ IOL Delivery System (Models: BIOLI-C, BIOLI-rC, BIOLI-D) to deliver intraocular lenses showed that the device 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 in the IOL approved labeling without affecting the functionality of the lens.

Package stability and performance stability test results met the defined acceptance criteria and requirements for a shelf-life claim of 5 years. Visual inspection, package seal and package integrity of the sterile barrier system of bioli™ IOL Delivery System met the requirements in accordance with ASTM F1980-2007(2011 reapproved). The post aging tests were carried out in accordance with ASTM F88-09, ASTM F1929-12, ISO 11737-2:2009, USP 35 and ASTM F1140/F1140M-2013.

Results from sterilization validation testing conducted in accordance with ISO 11135:2014 demonstrated that bioli™ IOL Delivery System is able to be sterilized using EtO sterilization parameters with residual EO found to be within safe levels post-aeration period.

A transport stability study was conducted according to requirements in ISO 2233:2001, ASTM D4169-16, ASTM F88/F88M-15, ASTM F2096-11, and ASTM F1929-15. The results demonstrated that bioli™ IOL Delivery System was able to

resist the physical damage caused by drop, vibration and short extreme temperature impacts during transportation.

— Clinical Tests: Not required for this device.

11. Conclusion

The resulting data from simulated surgical manipulation of bioli™ IOL Delivery System to deliver intraocular lenses showed that bioli™ (Models: BIOLI-C, BIOLI-rC, BIOLI-D) can successfully deliver Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the IOL approved labeling 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, we conclude that the bioli™ IOL Delivery System is substantially equivalent to the referenced legally marketed predicate device provided in this 510(k) premarket notification submission.