March 29, 2019

AST Products, Inc.
℅ Dr. David Lim
VP, R&D and Regulatory Affairs
9 Linnell Circle
Billerica, MA 01821

Re: K182965
Trade/Device Name: BL-Cart™ IOL Delivery Cartridge
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: February 14, 2019
Received: February 19, 2019

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. 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
Indications for Use

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.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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
   Regulatory Doctor™
   RCTC, LLC
   3955 Riner Road, Box 148
   Riner, VA 24149
   Tel: (800) 321-8567
   Email: info@regulatorydoctor.com

4. Product Name
   — Trade Name: BL-Cart™ IOL Delivery Cartridge (Model: Type 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
   — K063155: Monarch® III IOL Delivery System (D Cartridge)

7. Device Description
   BL-Cart™ IOL Delivery Cartridge (Model: Type D) is an intraocular lens (IOL) delivery
cartridge solution capable of supplying the ophthalmologist surgeon with a cartridge pre-coated with lubricious coating for use during a typical cataract surgery. The BL-Cart™ cartridge is used to deliver an approved IOL lens.

The BL-Cart™ IOL Delivery Cartridge and referenced predicate device, Monarch® III D cartridge, 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.

The BL-Cart™ IOL Delivery Cartridge comes with one pre-coated cartridge, packaged in a Tyvek pouch, placed in a 10 unit box as intended for marketing, and sterilized by ethylene oxide (EtO).

The BL-Cart™ IOL Delivery Cartridge and the referenced legally marketed predicate device share the same principal method to implant an intraocular lens into the eye.

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) and pioli™ IOL Delivery System (K172228).

8. Intended Use and Indications for Use

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 IOL approved labeling.

The BL-Cart™ IOL Delivery Cartridge 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

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Regulation No.</th>
<th>Product Code</th>
<th>Regulation Description</th>
<th>510(k) No.</th>
<th>Intended Use &amp; Indications for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL-Cart™ IOL Delivery Cartridge (Model: Type D)</td>
<td>AST Products, Inc.</td>
<td>886.4300</td>
<td>MSS</td>
<td>Intraocular Lens Guide</td>
<td>New device</td>
<td>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 IOL approved labeling.</td>
</tr>
<tr>
<td>Monarch® III IOL Delivery System (D Cartridge)</td>
<td>Alcon Research, Ltd.</td>
<td>886.4300</td>
<td>MSS</td>
<td>Intraocular Lens Guide</td>
<td>K063155</td>
<td>The MONARCH® III IOL Delivery System is used for implantation of ALCON® qualified ACRYSOF® intraocular lenses into the eye following cataract removal.</td>
</tr>
</tbody>
</table>
9. Technological Characteristics

The BL-Cart™ IOL Delivery Cartridge is an intraocular lens delivery cartridge used for progressive folding in combination with a reusable handpiece to deliver an intraocular lens into the eye for replacement of the human crystalline lens during cataract surgery. The device consists of a lubricious coated cartridge in preparation for intraocular lens loading and lens folding.

The BL-Cart™ IOL Delivery Cartridge 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*

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Design</th>
<th>Operating Principle</th>
<th>Biocomp.</th>
<th>Sterilization Method</th>
<th>Setting Used</th>
<th>Patient Contact</th>
<th>Recommended for Use With</th>
<th>Human Factors</th>
<th>Performance Criteria Met?</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL-Cart™ IOL Delivery Cartridge (Model: Type D)</td>
<td>A sterile, single-use disposable coated cartridge</td>
<td>The one-piece disposable cartridge is loaded into a reusable handpiece injection system and the IOL is pushed through the cartridge into the eye</td>
<td>Yes</td>
<td>ETO sterilization SAL level 1x10^-6</td>
<td>Hospital/Surgery center</td>
<td>Distal end of cartridge to place lens in eye</td>
<td>FDA-approved viscoelastic</td>
<td>For use by doctors only</td>
<td>Yes</td>
</tr>
<tr>
<td>Monarch® III IOL Delivery System (D Cartridge)</td>
<td>Monarch® III reusable handpiece and single-use, sterile coated cartridge</td>
<td>The one-piece disposable cartridge is loaded into a reusable handpiece injection system and the IOL is pushed through the cartridge into the eye</td>
<td>Yes</td>
<td>ETO sterilization</td>
<td>Hospital/Surgery center</td>
<td>Distal end of cartridge to place lens in eye</td>
<td>FDA-approved viscoelastic</td>
<td>For use by doctors only</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Table 3. *Device Comparisons – Materials*

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Device Materials</th>
<th>Standards Met</th>
</tr>
</thead>
</table>
10. Performance Data (Nonclinical and/or Clinical)

— Non-clinical Tests:

The BL-Cart™ IOL Delivery Cartridge 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 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 BL-Cart™ IOL Delivery Cartridge 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 BL-Cart™ IOL Delivery Cartridge, as well as lens opening time after folding. The BL-Cart™ 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 microscope and showed passing results, and were within dimensional specifications. BL-Cart™ also showed no damage after lens delivery.

The resulting data from simulated surgical manipulation of BL-Cart™ IOL Delivery Cartridge (Model: Type 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.

— Clinical Tests: Not required for this device.

11. Conclusion

The resulting data from simulated surgical manipulation of BL-Cart™ IOL Delivery Cartridge to deliver intraocular lenses showed that BL-Cart™ (Model: Type 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 BL-Cart™ IOL Delivery Cartridge is substantially equivalent to the referenced legally marketed predicate device provided in this 510(k) premarket notification submission.