November 20, 2018

Orbit Biomedical, Inc.
℅ Judy Gordon
Regulatory Affairs Consultant
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K182274
   Trade/Device Name: Orbit Subretinal Delivery System
   Regulation Number: 21 CFR 880.5860
   Regulation Name: Piston Syringe
   Regulatory Class: Class II
   Product Code: FMF, HMX
   Dated: September 14, 2018
   Received: September 17, 2018

Dear Judy Gordon:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Alexander Beylin -S
2018.11.20 14:06:07 -05'00'

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)
K182274

Device Name
Orbit Subretinal Delivery System

Indications for Use (Describe)
The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.

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 OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

| **APPLICANT:**          | Orbit Biomedical Inc.  
|                         | 300 Brookside Ave.  
|                         | Ambler, PA 19002 |
| **OFFICIAL CORRESPONDENT:** | Judy F. Gordon, D.V.M.  
|                         | ClinReg Consulting Services, Inc.  
|                         | 733 Bolsana Drive  
|                         | Laguna Beach, CA 92651  
|                         | Tel: (949) 715-0609  
|                         | judy@clinregconsulting.com |
| **DATE SUMMARY PREPARED:** | November 20, 2018 |
| **SIGNATURE:**          | [Signature Image] |
| **TRADE NAME:**         | Orbit Subretinal Delivery System |
| **COMMON NAME:**        | Manual Ophthalmic Surgical Instrument |
| **DEVICE CLASSIFICATION / CODE:** | FMF, Syringe, Piston  
|                         | Class II  
|                         | 21 CFR 880.5860 |
| **SECONDARY PRODUCT CODE:** | HMX, Ophthalmic Cannula |
| **PREDICATE DEVICE:**   | K023752  
|                         | BD Integra 1ml  
|                         | Syringe  
|                         | Class II  
|                         | 21 CFR 880.5860  
|                         | FMF |
| **REFERENCE DEVICE:**   | K010305  
|                         | Weiss Retinal Cannula  
|                         | Micon Surgical, Inc.  
|                         | Class I  
|                         | 21 CFR 886.4350  
|                         | HMX |
DEVICE DESCRIPTION

The Orbit Subretinal Delivery System (Figure 1) is designed for microinjection into the subretinal space. The Orbit Subretinal Delivery System is comprised of 2 kits: the Subretinal Access Kit and the Third Arm Kit.

![Figure 1: Orbit Subretinal Delivery System](image)

All Subretinal Access Kit components are supplied sterile and intended for single-use only and cannot be reused or resterilized. The Subretinal Access Kit contains the following device components:

**Subretinal Injection Cannula**: A sterile flexible ophthalmic cannula with an advanceable needle is used for subretinal access via the suprachoroidal space. The Subretinal Injection Cannula allows for consecutive injections. The first subretinal injection delivers either Balanced Salt Solution (BSS) or BSS® PLUS to create an “entry bleb” in the desired subretinal location. The second subretinal injection delivers a specific treatment “dose” (i.e., quantity) of BSS or BSS® PLUS into the entry bleb that was created with the first injection. The advanceable needle is available in 2 different configurations: straight or curved.

**Ophthalmic Marker**: A custom sterile ophthalmic marker is provided and is intended to be used with a commercially available sterile gentian violet ink marking pad. The marker is used to stain the sclera for positioning of suture loops and scleral incision.

**Syringes**: Two (2) identical sterile syringes (1 mL each) are provided, one for each fluid line: BSS line (used to create an entry bleb) and the DOSE line (used to deliver the BSS or BSS® PLUS treatment dose). Each syringe includes a barrel, a plunger rod, and a piston.

**Tubing Set**: An optional tubing set is supplied with each kit to allow the user the ability to connect to a commercially available vitreoretinal surgical console for pneumatic injection (vs. manual injection). A sterile tubing set connects to the 1 mL syringe and interfaces with the pressure regulator functionality of vitreoretinal surgical consoles.
The assembled Third Arm Kit functions as a “third arm” to stabilize the subretinal injection cannula and free the surgeon’s hands during the procedure. The Third Arm Kit (supplied non-sterile) is reusable and must be cleaned and sterilized prior to each use.

Together, the Subretinal Access Kit and the Third Arm Kit are to deliver the infusate (e.g., BSS, BSS® PLUS) to the subretinal space as described in the Instructions for Use.

**INDICATIONS FOR USE**

The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.

**TECHNOLOGICAL CHARACTERISTICS COMPARISON**

The technical features of the Subretinal Delivery System components are substantially equivalent to the features and intended use of the BD 1ml syringe (K023752), as well as the Weiss Retinal Cannula (K010305). The Subretinal Delivery System is manually operated for the controlled delivery of small amounts of fluid dispensed on the principle of exchanging volumes with the use of a piston syringe that has the same features and intended use of the predicate piston syringe.

The primary similarities and differences for the predicate device include:

- **Syringe configuration** – The syringe component of the Orbit Subretinal Delivery System shares the same primary components (i.e. syringe barrel, plunger and piston). The primary technological difference between the proposed and the predicate syringe devices is that the proposed device utilizes an injection cannula for fluid delivery instead of the needle connected to the syringe itself (predicate).

- **Syringe operating principle** – Both the proposed and predicate syringe(s) are manually operated by the user through the advancement and/or withdrawal of the syringe plunger within the barrel. Syringe content volume can be controlled by the user for both the proposed and predicate devices. These operating principles are identical to the vast majority of piston syringes currently on the market.

The technical features of the Orbit Subretinal Delivery System is also substantially equivalent to the Weiss Retinal Cannula which is presented as a reference device.

The primary similarities and differences for these devices include:

- **Cannula Tip design** - The rounded tip design of the Orbit cannula design is similar to the design of the reference device, which is designed for insertion. The Orbit cannula tip is made from a more flexible and lubricious material that contours more closely to the globe for smoother entry into the suprachoroidal space. Materials chosen for the proposed and reference devices are medical grade and were tested for biocompatibility.
- Needle advancement - As with the reference device however the SRDS needle rotates in order to advance vs. the slide mechanism of the reference device. The user has finer control of the needle advancement by this screw mechanism.

- The differences between the design of the subretinal cannula component of the Orbit Subretinal Access Kit and the Weiss Retinal Cannula (reference device) is that the proposed device is also provided with an ophthalmic marker and a reusable cannula holder, called the Third Arm Kit that frees the surgeon’s hands during the procedure.

  The Orbit Subretinal Injection Cannula and the Weiss Retinal Cannula provide a cylindrical fluid pathway designed to administer pre-assigned fluid volumes to the subretinal space.

The minor differences in design features or technological characteristics between the Orbit Subretinal Delivery System and the predicate and reference devices do not introduce new or unique potential adverse events (i.e., hazards) and therefore does not raise new issues of safety and effectiveness.

Table 1 on the following page provides additional comparison between the components of the proposed device (Orbit Subretinal Delivery System) and the predicate and reference devices.
### TABLE 1
#### DEVICE COMPARISON

<table>
<thead>
<tr>
<th>Feature</th>
<th>Orbit Subretinal Delivery System Proposed Device</th>
<th>BD Integra 1mL Syringe K023752 Predicate Device</th>
<th>Weiss Retinal Cannula K010305 Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Orbit Biomedical, Inc.</td>
<td>BD</td>
<td>Micron Surgical, Inc.</td>
</tr>
<tr>
<td>Device Classification</td>
<td>Class II</td>
<td>Class II</td>
<td>Class I</td>
</tr>
<tr>
<td>Device Product Code</td>
<td>FMF; HMX</td>
<td>FMF</td>
<td>HMX</td>
</tr>
<tr>
<td>Regulation Description</td>
<td>Cannula, Ophthalmic</td>
<td>Syringe, Piston</td>
<td>Cannula, Ophthalmic</td>
</tr>
<tr>
<td>Regulation</td>
<td>21 CFR 886.4350</td>
<td>21 CFR 880.5860</td>
<td>21 CFR 886.4350</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.</td>
<td>The BD Integra Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin.¹</td>
<td>The Weiss Retinal Cannula is used for microinjection into the subretinal space, intraretinal space or intravascular retinal space.</td>
</tr>
</tbody>
</table>

#### Syringe

<table>
<thead>
<tr>
<th>Feature</th>
<th>Orbit Subretinal Delivery System Proposed Device</th>
<th>BD Integra 1mL Syringe K023752 Predicate Device</th>
<th>Weiss Retinal Cannula K010305 Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Single use, small amounts of fluid injection</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Configuration</td>
<td>Standard 3-piece piston syringe constructed with a barrel, piston, plunger</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Operation Mode</td>
<td>Manually operated by the advancement of the syringe plunger within the barrel</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Materials</td>
<td>Common materials chosen, medical grade, low extractable polymer</td>
<td>Not disclosed in 510(k) summary</td>
<td>N/A</td>
</tr>
<tr>
<td>Volume</td>
<td>1 mL; controlled through dose clips</td>
<td>1 ml; user controlled by use of depth markings</td>
<td>N/A</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>ISO 10993-1 compliance</td>
<td>Same</td>
<td>N/A</td>
</tr>
</tbody>
</table>

¹ Complete Indications for Use: The BD Integra™ Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy. The insulin syringe has scale lines in insulin units and is used for insulin injections. The tuberculin syringe can be used for any of the 3 types of common injections (intra-dermal, intra-muscular or subcutaneous). The BD Integra™ 1 mL Syringe has a permanently attached needle. The BD Integra 1 mL Syringe contains a tool used to cut through the hub and stopper allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle syringe combination.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Orbit Subretinal Delivery System Proposed Device</th>
<th>BD Integra 1mL Syringe K023752 Predicate Device</th>
<th>Weiss Retinal Cannula K010305 Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>EO Sterility Assurance Level (SAL) $10^{-6}$</td>
<td>Not disclosed in 510(k) summary</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Subretinal Injection Cannula</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexible Ophthalmic Cannula</td>
<td>YES</td>
<td>N/A</td>
<td>YES</td>
</tr>
<tr>
<td>Suprachoroidal Cannulation</td>
<td>YES</td>
<td>N/A</td>
<td>Unknown</td>
</tr>
<tr>
<td>Advanceable Needle</td>
<td>YES</td>
<td>N/A</td>
<td>YES</td>
</tr>
<tr>
<td>Subretinal Access and subretinal injection</td>
<td>YES</td>
<td>N/A</td>
<td>YES</td>
</tr>
<tr>
<td>Catheter/Cannula materials of manufacture</td>
<td>PEBAX/PROPELL (outer sheath), Stainless Steel (insert)</td>
<td>N/A</td>
<td>304 Stainless steel, polyester tubing (outer sleeve)</td>
</tr>
<tr>
<td>Catheter/Cannula dimensions</td>
<td>1.6mm x 8mm (oval cross section)</td>
<td>N/A</td>
<td>200 microns</td>
</tr>
<tr>
<td>Advanceable needle materials of manufacture</td>
<td>Nitinol</td>
<td>N/A</td>
<td>Borosilicate glass</td>
</tr>
<tr>
<td>Advanceable needle size</td>
<td>0.012 in (approx. 305 microns) OD</td>
<td>N/A</td>
<td>70 microns OD / 50 microns ID</td>
</tr>
<tr>
<td>Needle/cannula advancing mechanism</td>
<td>Mechanical: Rotating knob and internal cam for linear translation</td>
<td>N/A</td>
<td>Retraction of polymeric tube to expose microneedle</td>
</tr>
<tr>
<td>Needle/cannula full extension length</td>
<td>Up to 4.5 mm</td>
<td>N/A</td>
<td>3 mm</td>
</tr>
<tr>
<td>Infusion line material</td>
<td>Tecoflex 72A (polyurethane)</td>
<td>N/A</td>
<td>Polyethylene</td>
</tr>
<tr>
<td>Atraumatic features</td>
<td>Molded tip, retractable needle, lubricious cannula material (PROPELL, within sheath material)</td>
<td>N/A</td>
<td>Retractable needle, polymeric tubing</td>
</tr>
<tr>
<td>Infusion port</td>
<td>Luer connector</td>
<td>N/A</td>
<td>Luer connector</td>
</tr>
<tr>
<td>Depth markings</td>
<td>5-20mm in 5mm increments</td>
<td>N/A</td>
<td>Unknown</td>
</tr>
<tr>
<td>Provided single use, sterile packed</td>
<td>YES except for Third Arm Kit</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>Gamma (subretinal injection cannula set, tubing set)</td>
<td>Not disclosed in 510(k) Summary</td>
<td>Ethylene Oxide</td>
</tr>
</tbody>
</table>
**Performance Data**

The descriptive characteristics of the Orbit Subretinal Delivery System are well-defined and adequate to ensure equivalence to the predicate devices. Additionally, verification and validation testing of the Orbit Subretinal Delivery System represents a comprehensive evaluation for the suitability for use.

The following tests were successfully performed with the device components to establish substantial equivalence of the Subretinal Delivery System to the predicate and reference devices:

- **Biocompatibility testing in accordance with ISO 10993-01 including Cytotoxicity (per ISO10993-5 and USP<87>), Sensitization (per ISO10993-10), Irritation, intracutaneous (per ISO10993-10), Irritation, primary eye (per ISO10993-10) and Systemic toxicity (per ISO10993-11).**
- **Sterilization conditions were validated on the Injection Cannula Set and Tubing Set in accordance with ANSI/AAMI/ISO 11137-2:2013 to provide a Sterility Assurance Level of 10-6, and with ISO 11135:2014 for the syringe set. EO and ECH residuals testing was also performed with the syringe set. Testing demonstrated product performance met all prior established acceptance criteria.**
- **Cleaning and disinfection validation was performed per FDA Guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” and confirmed that the Third Arm Kit meets the established cleaning and disinfection requirements.**
- **Packaging qualification was performed as part of the transportation studies to demonstrate that whole package physical integrity requirements and seal integrity requirements for the Subretinal Access Kit packaging were met.**
- **Real-time shelf life testing was conducted as part of the transportation and design verification test program for the sterile device to establish a 29 month expiration date for the Subretinal Access Kit.**
- **Post-distribution performance testing of the Subretinal Access Kit Testing included:**
  - **Syringe Set testing included visual inspection of the device as well as package integrity testing.**
  - **Tubing Set was tested for leak pressure, tensile strength, dimensional integrity.**
  - **Subretinal Injection Cannula set was tested for flexural stiffness, flow rate, dimensional integrity, assembly tensile strength, and leak pressure.**
  
  All tests passed pre-established test criteria and demonstrate that the Subretinal Access Kit performance is maintained following distribution.
- **Simulated use evaluation of the Subretinal Delivery Device was designed to confirm the injection of saline forming a subretinal bleb. The injections were performed in a porcine model in eight (8) procedures with injection volumes of 50μl, 100μl, 200μl, and 300μl.**
- **Functionality of the Third Arm Kit was also tested to verify stability to the injection cannula upon simulated operation during use, verification of the dose clip delivery accuracy as well as the durability of the device components. All tests passed.**
CONCLUSION
The Orbit Subretinal Delivery System meets all product design requirements and applicable standards. The device shares the same intended use, key technological characteristics as the predicate device and serves the same physiological purpose as a reference device. Therefore, the device has been shown to be substantially equivalent to the predicate devices.