July 14, 2020

Orbit Biomedical
% Debe Deck
Regulatory Consultant
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, California 92651

Re: K200325
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: February 7, 2020
Received: February 10, 2020

Dear Debe Deck:

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,

Elvin Ng
Acting Assistant 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)*
K200325

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 Avenue Building 18, Ste 180 Ambler, PA 19002 (267) 523-2100
OFFICIAL CORRESPONDENT:	Debe Deck ClinReg Consulting Services, Inc. (949) 375-4387 debe@clinregconsulting.com
DATE SUMMARY PREPARED:	February 07, 2020
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 Class I 21 CFR 886.4350
PREDICATE DEVICE:	K182274 Orbit Subretinal Delivery System FMF, Syringe, Piston Class II 21 CFR 880.5860

DEVICE DESCRIPTION

The Orbit Subretinal Delivery System **(Figure 1)** is designed for microinjection into the subretinal space. The Orbit Subretinal Delivery System (SDS) is comprised of 3 primary component sets including the Subretinal Injection Device Set, the Tubing Set, and the Dosing Set.

Figure 1: Orbit Subretinal Delivery System

Each Orbit SDS Set contains sterile single-use only components. The Subretinal Injection Device set includes the magnetic pad, ophthalmic marker, and subretinal injection device (SID). The Tubing Set includes the components for priming the BSS line and pneumatic BSS control via a vitreoretinal surgical console. The Dosing Set includes the syringe for delivery of a precise dose of Balanced Salt Solution (BSS) or BSS PLUS® infusate. Each of the set components are described below, along with their principles of operation within the context of the intended use.

Subretinal Injection Device (SID) Set: A sterile, flexible ophthalmic cannula with an advanceable needle is used for subretinal access via the suprachoroidal space. The Subretinal Injection Device allows for consecutive injections. The first subretinal injection delivers 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 SID is fitted with an internal magnet designed to allow for secure, simple attachment to the magnetic pad that adheres to a sterile drape that is placed onto the patient's forehead during preparation.

Magnetic Pad: The SID Set includes an adhesive-backed magnet pad with a flexible steel core. The magnet inside the SID is attracted to the steel core, allowing for secure placement and positioning. The magnetic pad is adhered directly to the sterile drape that has been securely placed on the patient's forehead.

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

Tubing Set: A Tubing Set is supplied to allow the user the ability to connect to a commercially-available vitreoretinal surgical console for pneumatic injection (vs. manual injection). The

Tubing Set includes the Tubing Assembly, a sterile 1 mL syringe (i.e., the BSS Syringe) that is used to create an entry bleb and two (2) Snap Collars that connect the sterile Tubing Assembly to the BSS Syringe. The proximal end of the Tubing Assembly is fitted with a CPC connector. A female to male CPC adapter is also included. The CPC connectors interface with the viscous fluid control (VFC) functionality of vitreoretinal surgical consoles.

Dosing Set: The Dosing Set includes the Dose Syringe used to deliver the BSS or BSS PLUS treatment dose, and two (2) Tubing Clamps.

Together, the Subretinal Injection Device, Tubing, and Dosing Sets are used 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

Technological characteristics of the Orbit Subretinal Delivery System described in this 510(k) are substantially equivalent to the predicate device (Orbit Subretinal Delivery Device, K182274) that share the same mode of operation in the delivery of fluid into the subretinal space.

The predicate device (Orbit Subretinal Delivery System cleared under K182274) included a non-sterile reusable Third Arm Kit that functioned as a “third arm” to hold the subretinal injection cannula housing stable during the procedure. The Third Arm Kit required cleaning and sterilization prior to each use. One of the primary modifications to the Orbit Subretinal Delivery System proposed in this 510(k) is the elimination of the reusable Third Arm Kit, replacing it with components in the single-use sterile Subretinal Injection Device (SID) Set and Dosing Set.

The proposed Orbit SDS eliminates all reusable components and uses an internal magnet (encased within the SID housing) to provide stability. During setup the magnetic pad is adhered directly on a sterile drape, securely positioned on the patient’s forehead. The SID is then placed on the magnetic pad.

Other modifications are being made to accommodate the improved device design, support material procurement, and to improve handling during the manufacturing process.

Table 1 on the following page provides additional comparison between the components of the proposed Orbit Subretinal Delivery System and the predicate device.

TABLE 1
TECHNOLOGICAL COMPARISON OF THE ORBIT SUBRETINAL DELIVERY SYSTEM TO THE PREDICATE DEVICE

Feature	Orbit Subretinal Delivery System K182274	Orbit Subretinal Delivery System Proposed	Modified Y/N
Manufacturer	Orbit Biomedical, Inc.	Orbit Biomedical, Inc.	No
Device Classification/Code	Class II FMF, Syringe, Piston 21 CFR 880.5860	Class II FMF, Syringe, Piston 21 CFR 880.5860	No
Secondary Product Classification/Code	Class I HMX, Ophthalmic Cannula 21 CFR 886.4350	Class I HMX, Ophthalmic Cannula 21 CFR 886.4350	No
Indications for Use	The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.	The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.	No
Principle of Operation	Manual operation of syringe for delivery of infusate	Manual operation of syringe for delivery of infusate	No
How Supplied	Sterile, single use only (subretinal injection cannula set, tubing set, syringe set) Reusable (Third arm assembly)	Sterile, single use only (all components)	Yes, all components of the proposed Orbit SDS are provided sterile and intended for single use only. The reusable third arm assembly from the predicate device configuration has been eliminated in the proposed device.
Method of Sterilization	Ethylene Oxide Sterilization (syringe set); Gamma Irradiation (subretinal injection cannula set, tubing set)	Ethylene Oxide sterilization (all components)	Yes, all components are now sterilized by EO

PERFORMANCE DATA

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

The following tests were successfully performed with the device components to establish substantial equivalence of the Orbit SDS to the predicate device:

- Biocompatibility testing in accordance with ISO 10993-01 including Cytotoxicity (per ISO10993-5 and USP<87>), Sensitization (per ISO10993-10), Ocular Irritation (per ISO10993-10), Systemic toxicity (per ISO10993-11) and Material Mediated Pyrogenicity (per ISO10993-11).
- Sterilization conditions were validated for the Orbit Subretinal Delivery System to provide a Sterility Assurance Level of 10^{-6}, in accordance with ISO11135. EO and ECH residuals testing was also performed in accordance with ISO10993-7. Testing demonstrated product performance met all prior established acceptance criteria.
- Packaging qualification was performed as part of the transportation and environmental conditioning studies for the device to demonstrate that whole package physical integrity requirements and seal integrity requirements for the modified Orbit SDS packaging were met.
- Accelerated shelf life testing was conducted as part of the transportation and design verification test program for the sterile device to establish the expiration date for the Orbit SDS.
- Post-distribution, post-accelerated aging performance testing for each set of the Orbit SDS was completed. Testing demonstrated that product performance met all acceptance criteria.
- Simulated use testing of the Orbit SDS was designed to confirm the injection of an infusate to form a subretinal bleb.

All tests passed their respective pre-established test criteria and demonstrate that the Orbit SDS performance is maintained following distribution.

CONCLUSION

The Orbit Subretinal Delivery System meets all product design requirements and applicable standards. The device shares the same intended use and key technological characteristics as the predicate device. Therefore, the device has been shown to be substantially equivalent to the predicate device.