April 26, 2021

MedOne Surgical, Inc.
% Darla Elkin
President
Elkin RC, LLC
42 North Chantsong Circle
The Woodlands, Texas 77382

Re: K203264
Trade/Device Name: MicroDose Injector
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 15, 2021
Received: March 17, 2021

Dear Ms. Elkin:

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
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)*
K203264

Device Name
MicroDose™ Injector

Indications for Use *(Describe)*
The MicroDose Injector is indicated for low volume ophthalmic injections 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
MedOne Surgical, Inc. MicroDose™ Injector

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, section 807.92

Sponsor's Name and Address: MedOne Surgical, Incorporated
670 Tallevast Drive
Sarasota, Florida 34243

Contact Person: Darla J. Elkin
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Date Summary Prepared November 4, 2020

Device Trade Name: MicroDose™ Injector

Common Name: Syringe, Piston

Product Code: FMF

Device Classification: Class II

Predicate Devices: K200325
Orbit Subretinal Delivery System

Device Description:

The MicroDose Injector is designed for low volume ophthalmic injection into the subretinal space. It consists of one (1)1mL syringe and one (1) connector, which is joined to VFC tubing that is attached to a pneumatic air source, enabling a surgeon control for administering subretinal injections. The device is supplied sterile and intended for single-use only and cannot be reused or resterilized.

Indications for Use:

The MicroDose is indicated for low volume ophthalmic injection into the subretinal space.

Technological Characteristics and Substantial Equivalence

The technical features of the MicroDose Injector are substantially equivalent to the predicate device (K200325) intended use/indication for use, materials, technological characteristics, and labelling.

Table 1 on the following page provides the comparison between the MedOne MicroDose Injector and the predicate device.

Table 1. Comparison of the Technological Characteristics of the New Device and Predicate Device:

Feature	MicroDose™ Injector Proposed Device	Orbit Subretinal Delivery System Predicate Device
K#	K203264	K200325
Device Classification/Code	Class II FMF, Syringe, Piston 21 CFR 880.5860	Class II FMF, Syringe, Piston 21 CFR 880.5860
Secondary Product Classification/Code	N/A	Class I HMX, Ophthalmic Cannula 21 CFR 886.4350
Indication for Use	The MicroDose is indicated for low volume ophthalmic injection into the subretinal space.	The Orbit Subretinal Delivery System is indicated for microinjection into the subretinal space.
How Supplied	Sterile, single use only.	Sterile, single-use only.
Configuration	1mL Syringe (syringe barrel and piston - plunger removed) and Connector	1mL Syringe (syringe barrel, plunger and piston), cannula, tubing set, CPC adapter, magnetic pad, ophthalmic marker
Mode of Operation	Pneumatic	Pneumatic or Manual
Volume	1mL	1mL
Fluid Delivery	Cannula supplied separately	Cannula supplied with device
Biocompatibility	Meets ISO 10993-1	Meets ISO 10993-1

The MicroDose shares the same intended use, the same or similar device operation, and overall technical and functional capabilities to the predicate device and meets applicable standards. Therefore, the MicroDose is substantially equivalent to the predicate device, as outlined in Table 1. Any difference between the MicroDose and the predicate device has no significant influence on safety or effectiveness of the MicroDose Injector.

The primary similarities and differences for the predicate device include:

- Syringe configuration – The syringe component of the MicroDose shares the same components (1mL syringe barrel, and piston (plunger rod removed) as the Orbit syringe (1mL syringe barrel, plunger rod and piston). The primary technological difference is the MicroDose does not require use of a plunger rod and is removed during manufacture while the Orbit device has a removable plunger rod if the user wishes to operate the syringe pneumatically.
- Both devices use an injection cannula for fluid delivery. The cannula is supplied with the predicate device; the cannula is supplied separately from the MicroDose.
- Syringe operating principle – Both devices are used with a pneumatic air source. A technological difference is that the predicate device can also be used manually.
- The Orbit device has a magnet encased within the SID housing to provide stability. Use of a magnet is not required for the MicroDose.

Performance Data

The following tests were successfully performed with the device to establish substantial equivalence to the predicate devices:

- Biocompatibility testing in accordance with ISO 10993-1 including Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Irritation, Intracutaneous (ISO 10993-10), Irritation, Ocular (ISO 10993-10), Systemic toxicity (ISO 10993-11) and Pyrogenicity (ISO 10993-11).
- Sterilization validation in accordance with ISO 11137-1 and ISO 11137-2 to provide a Sterility Assurance Level of 10^{-6}.
- Shelf-life testing was conducted for the sterile device to establish a 5 year expiration date.
- Package and performance testing was performed post shipping to ensure package integrity and functionality of the device. All tests passed.

Conclusion

The MicroDose™ Injector was found to be substantially equivalent to the predicate device as it 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.