February 19, 2021

OcuJect, LLC
Rebecca Pine
Official Correspondent
1441 Avocado Ave, Suite 204
Newport Beach, California 92660

Re: K202432
Trade/Device Name: MiniLoad Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 19, 2021
Received: January 21, 2021

Dear Rebecca Pine:

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,

Rumi Young
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202432

Device Name
MiniLoad Syringe

Indications for Use *(Describe)*
The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from the body.

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

I. SUBMITTER

OcuJect, LLC
1441 Avocado Ave, Suite 204
Newport Beach, CA 92660

Contact person: Rebecca K Pine
Phone: (760) 809-5178
Fax: (760) 290.3216
Date prepared: February 10, 2021

II. DEVICE

Name of the device: MiniLoad Syringe
Common of usual name: Syringe
Classification name: Syringe, Piston
Regulatory Class: II
Product Code: FMF
Regulation: 21 CFR 880.5860

III. PREDICATE DEVICE

NORM-JECT Syringe (K101547)- primary predicate
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The MiniLoad Syringe is a device intended to provide a means of general use fluid injection and aspiration. The device is comprised of a hollow barrel with gradient markings and a plunger. The barrel component has a male slip tip end for the fitting of a compatible needle. The device is available in a 1ml volume.

V. INDICATIONS FOR USE

The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from the body.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the MiniLoad Syringe are highly analogous to the technological characteristics of the NORM-JECT Syringe (K101547).

The similarities and differences are illustrated in the table below:

		MiniLoad Syringe	**NORM-JECT (K101547)**
Proprietary Name		MiniLoad Syringe	NORM-JECT Syringe
Product Code		FMF	FMF
Indications for Use		The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from the body	The HSW NORM-JECT syringes are intended to be used to inject into, or withdraw fluids from the body. The 1 ml syringe with a purple plunger, labeled with BOTOX® is exclusively produced for use with BOTOX® Cosmetic (onabotulinumtoxinA)
Intended Users		SAME	Clinicians
Principle of operation		SAME	Manual advancement and withdrawal of the plunger within the barrel
Device components		SAME	Barrel Plunger
Materials	Barrel	Polypropylene	Unknown
	Plunger	Polyethylene	Unknown
	Lubricant	Oleamide	Unknown
Barrel Size Volume (ml)		SAME	1ml
Barrel length		~ 85mm	Unknown
Barrel outside diameter		~ 6.4mm	Unknown
Barrel inside diameter		~ 4.6mm	Unknown
Barrel color		Transparent	Unknown
Barrel printing		Black ink	Unknown
Plunger length		93.4 mm	Unknown
Plunger color		Blue	Purple
Graduation		Printed, ISO 7886-1 compliant	Unknown
Tip type		Slip tip	Unknown
Sterilization method		EO	Unknown
SAL		10^{-6}	Unknown
Sterilization Validation Standard		SAME	ISO 11135-1
Biocompatibility		ISO 10993-1 (Biological Evaluation) ISO 10993-4 (Hemocompatibilty) ISO 10993-5 (cytotoxicity) ISO 10993-7 (EO residuals) ISO 10993-10 (Sensitization) ISO 10993-10 (Irritation) Acute Systemic Toxicity (ISO 10993-11) Materials Mediated Pyrogenicity (ISO 10993-10)	ISO 10993-1 (Biological Evaluation) ISO 10993-4 (Hemocompatibilty) ISO 10993-5 (cytotoxicity) ISO 10993-7 (EO residuals) ISO 10993-10 (Sensitization) ISO 10993-10 (Irritation) Acute Systemic Toxicity (ISO 10993-11)
Performance Data		SAME	ISO 7886-1

The MiniLoad Syringe and the NORM-JECT Syringe both have a barrel component which provides a holding area for liquid and a plunger for the expulsion of the liquid from the barrel.
All device barrels are fabricated from polymers demonstrated to be biocompatible.
The plunger of the MiniLoad syringe is blue and the NORM-JECT plunger is purple.
Any material, lubricant or color differences do not raise any safety concerns because the device complies with biocompatibility requirements per ISO 10993-1.
Both the MiniLoad and the NORM-JECT syringes are available in a 1 ml capacity.

Both the MiniLoad Syringe and the NORM-JECT syringe are in conformance with the requirements of ISO 7886-1.

VII. PERFORMANCE DATA

The following performance data are available in support of the substantial equivalence.

- Freedom from Extraneous Matter (ISO 7886-1)
- Lubricant Quantification (ISO 7886-1)
- Plunger Stop Detachment (ISO 7886-1)
- Barrel Flange to Plunger Distance (ISO 7886-1)
- Dead Space (ISO 7886-1)
- Freedom from leakage (ISO 7886-1)
- Piston operational force (ISO 7886-1)
- Plunger Fit (ISO 7886-1)
- Packaging Validation (ISO 11607-1)

The subject device met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the MiniLoad Syringe was found to have a safety and effectiveness profile that is similar to the predicate device.

<u>Biocompatibility</u>
In accordance with ISO 10993-1, the needle is classified as: Externally communicating, indirect blood path with limited contact duration (≤ 24 hours).The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP <788>Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Shipping and Shelf-Life

The MiniLoad Syringe is sterilized utilizing ethylene oxide (EO). The sterilization cycle was validated per ISO 11135 Overkill (half-cycle) method, and the MiniLoad Syringe was adopted into the validated cycle utilizing AAMI TR28:2016. The ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals for the MiniLoad Syringe are ≤4mg/device and ≤ 9mg/device, respectively. The MiniLoad Syringe was evaluated for bacterial endotoxin utilizing the USP <85> gel clot method.

- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15

- Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

VIII. CONCLUSIONS

The design testing performed for the MiniLoad Syringe demonstrated that the performance of the device is equal to the legally marketed predicate device NORM-JECT (K101547).