October 13, 2021

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

Re: K212544
Trade/Device Name: MiniLoad Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: September 13, 2021
Received: September 15, 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,

for Alans Stevens
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)*
K212544

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.

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K212544 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: October 13, 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

MiniLoad Syringe (K202432)- primary predicate

PLPT LDV (Low Dead Volume) Sterile Syringe (K210443)- reference device

IV. DEVICE DESCRIPTION

The MiniLoad Syringe is a device intended to provide a means of fluid injection and aspiration. The device is comprised of a hollow barrel with gradient markings and a plunger. The barrel component is available in two configurations: 1) with a male slip tip end 2) with a luer-lock end; both 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 modified MiniLoad Syringe are highly analogous to the technological characteristics of the cleared MiniLoad Syringe (K202432).
The similarities and differences are illustrated in the table below:

		Subject device	Primary Predicate	Comparison
		MiniLoad Syringe Syringe	**MiniLoad Syringe (K202432)**	
Proprietary Name		MiniLoad Syringe	MiniLoad Syringe	
Product Code		FMF	FMF	
Indications		The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from the body	The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from the body	SAME
Intended Users		Clinicians	Clinicians	SAME
Principle of operation		Manual advancement and withdrawal of the plunger within the barrel	Manual advancement and withdrawal of the plunger within the barrel	SAME
Device components		Syringe Barrel Plunger	Syringe Barrel Plunger	SAME
Materials	Barrel	Polypropylene BorMed HF840MO Cas # 9300-07-0	Polypropylene GM1600E	SAME
	Plunger	Polyethylene blue pigment P83424	Polyethylene blue pigment P83424	SAME
	Lubricant	Oleamide	Oleamide	SAME
Barrel Size Volume (ml)		1mL	1mL	SAME
Barrel length		~ 85mm	~ 85mm	SAME
Barrel outside diameter		~ 6.4mm	~ 6.4mm	SAME
Barrel inside diameter		~ 4.6mm	~ 4.6mm	SAME
Barrel color		Transparent	Transparent	SAME
Barrel printing		Black ink	Black ink	SAME
Plunger length		93.4 mm 85.3 mm	93.4 mm	Difference #..1
Plunger color		Blue	Blue	SAME
Graduation		Printed, ISO 7886-1 compliant	Printed, ISO 7886-1 compliant	SAME
Tip type		Luer slip Luer lock	Luer slip	Difference #2
Dead space specification		≤ 0.023mL with 95% confidence/95% reliability	ISO 7886-1 compliant	Difference #3
Sterilization method		EO	EO	SAME
SAL		10^{-6}	10^{-6}	SAME
Sterilization Validation Standard		ISO 11135-1	ISO 11135-1	SAME

	Subject device	Primary Predicate	Comparison
	MiniLoad Syringe Syringe	**MiniLoad Syringe (K202432)**	
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) Materials Mediated Pyrogenicity (ISO 10993-10)	SAME
Performance Data	ISO 7886-1 ISO 83069-7	ISO 7886-1	Difference #2

Difference #1: The subject device has a shorter plunger length. Differences addressed through testing per ISO 7886-1:2017.
Difference #2: The subject device has a luer lock connector. Differences addressed through testing per ISO 80369-7.
Difference #3: Subject device has dead space specification of ≤ 0.023mL. Differences addressed through performance testing.

The vast majority of the technological characteristics of the modified MiniLoad Syringe remain the same as the technological characteristics of the existing cleared MiniLoad Syringe (K202432). The differences do not raise different questions of safety and effectiveness.

Although the plunger/syringe interface remains the same for the modified Miniload Syringe and the existing MiniLoad Syringe, the modified MiniLoad will be labeled as a "low dead space" syringe. The dead space specification of ≤ 0.023mL with 95% confidence/95% reliability is in alignment with the specification established in the legally marketed device PLPT LDV (Low Dead Volume) Sterile Syringe (K210443).

The biocompatibility testing in conjunction with the performance test data per ISO 7886-1 and ISO 80369-7 demonstrate that the minor changes to the barrel polypropylene material as well as the addition of the 85.3mm plunger and luer-lock configuration have no adverse effect on the established safety and performance characteristics of the device and demonstrate substantial equivalence.

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)
- Luer connector (ISO 80369-7)
- Biocompatibility [External communicating device – Blood path indirect; limited (<24hr) contacting]
    - 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)
    - ISO 10993-11 (Acute Systemic Toxicity)
    - ISO 10993-10 Materials Mediated Pyrogenicity)

Through biocompatibility and performance bench testing results, it has been demonstrated that the subject device is as safe and effective as the predicate device, MiniLoad Syringe(K202432). The subject device is similar to the predicate device with respect to the intended use, target populations, and principles of operation. The identified technological differences between the devices do not raise any new questions of safety or effectiveness. Thus, the MiniLoad Syringe is substantially equivalent.

VIII. CONCLUSIONS

The design testing performed for the modified MiniLoad Syringe demonstrated that the performance of the device is equal to the legally marketed predicate devices