September 30, 2021

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

Re: K212805
Trade/Device Name: SteriCap™ Mini Needle and Standard Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 31, 2021
Received: September 2, 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 Alan 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)*
K212805

Device Name
SteriCap™ Mini Needle and standard needles

Indications for Use *(Describe)*
The SteriCap™ Mini Needle and standard needles are intended for use with a luer-tip syringe (e.g. luer-lock or slip-tip luer syringe) for the administration of drugs.

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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K212805 510(k) Summary

DATE
9/30/2021

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
Email: beky@cox.net

II. DEVICE
Name of the device: SteriCap Mini Needle and Needles
Common of usual name: Needle
Classification name: Single lumen hypodermic needle
Regulatory Class: 2
Product Code: FMI
Regulation: 21 CFR 880.5570

III. PREDICATE DEVICE
SteriCap Mini Needle (K183016)- primary predicate
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION
The SteriCap® Mini Needle ("SteriCap®") and Needles ("Needles") are devices intended to provide a means of fluid injection and aspiration to and from the body. The devices are a single lumen needle. For SteriCap® Mini Needle, the needle has a spring-actuated sliding cap, which protects the needle prior to use. For Needles, the needle is covered by a removable clear cap.
The additional gauges and lengths of the product family included in this submission are 30G/31G/33Gx 6mm and 31G / 33G x 4 mm. The additional gauges and lengths of the Needle included in this submission are 29G/30G/31G x 13 mm and 33G x 8 mm.

V. INDICATIONS FOR USE
The SteriCap Mini Needle and standard Needles are intended for use with a luer-tip syringe (e.g. luer- lock or slip-tip luer syringe) for the administration of drugs

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the modified SteriCap Mini Needle and Needles product family are highly analogous to the technological characteristics of the cleared SteriCap Mini Needle (K183016).

The similarities and differences are illustrated in the tables below:

Characteristics	**SteriCap Mini Needle K183016**	**SteriCap Mini Needle and Needle K212805**
Indications for Use	The SteriCap™ Mini Needle is a device intended for use with a luer-tip syringe (e.g. luer-lock or slip-tip syringe) for administration of drugs	The SteriCap Mini Needle and standard needles are intended for use with a luer-tip syringe (e.g. luer-lock or slip-tip luer syringe) for the administration of drugs.
Prescription Only or OTC	RX	RX

The indications for use statement for the subject device is identical to the predicate device.

	SteriCap Mini Needle (K183016)	**SteriCap Mini Needle and Needle (subject device)**	**Similarities/ differences**
Functional Construct	Single lumen needle	Single lumen needle	SAME
Principle of Operation	Connects to a luer type syringe to serve as a conduit for the movement of fluid	Connects to a luer type syringe to serve as a conduit for the movement of fluid	SAME
Design/ Const.	Needle Assembly (cannula, needle hub, spring loaded needle cap) Designed to fit standard 6% luer fittings	Needle Assembly (cannula, needle hub, spring loaded needle cap) Designed to fit standard 6% luer fittings	SAME
Materials	Cannula- Stainless steel Lubricant- Silicone Adhesive- polyacrylate Hub- polypropylene Needle Cap- polypropylene Spring- stainless steel	Cannula- Stainless steel Lubricant- Silicone Adhesive- polyacrylate Hub- polypropylene Needle Cap- polypropylene Spring- stainless steel (Mini Needle only)	SAME
Needle Taper	None	None	SAME

	SteriCap Mini Needle (K183016)	SteriCap Mini Needle and Needle (subject device)	Similarities/ differences
Needle Length-total	20 mm	<u>SteriCap Mini Needle</u> 19.5mm 20 mm 21.5mm <u>Needle</u> 16mm 20.5mm	Different (see Comment 1)
Needle Length-Exposed	5.5mm	<u>SteriCap Mini Needle</u> 5.5mm 6 mm 4 mm <u>Needle</u> 13 mm 8 mm	Different (see Comment 1)
Needle Gauge	33G 32G 30G 29G 27G 25G 23G	<u>SteriCap Mini Needle</u> 33G x 5.5mm 32G x 5.5mm 30G x 5.5mm 29G x 5.5mm 27G x 5.5mm 25G x 5.5mm 23G x 5.5mm 30G x 6mm 31G x 6mm 33G x 6mm 31G x 4mm 33G x 4mm <u>Needle</u> 29G x 13mm 30G x 13mm 31G x 13mm 33G x 8mm	Different (see Comment 2)
Tip Configuration	Lancet Bevel	Lancet Bevel	SAME
Wall Type	Std wall	Std wall	SAME
Sterilization	Ethylene oxide	Ethylene oxide	SAME
How provided	Sterile, single use	Sterile, single use	SAME
Sterile barrier	Blister pouch	Blister pouch	SAME

<u>Comment 1:</u> The additional exposed needle lengths for the product family, namely 4mm, 6mm, 8mm and 13mm are consistent with other commercially available hypodermic needles. The 4mm and 6mm lengths are highly similar to the existing Mini Needle length (e.g. 5.5mm). The 8mm and 13mm lengths are highly similar to other standard hypodermic needle lengths. The overall length of the needle have been modified based on the new exposed lengths. In the case of the 19.5mm and 21.5mm

overall lengths, these lengths are highly similar to the existing Mini Needle overall length of 20mm. The addition of the 16mm and 20.5mm are highly similar to other standard hypodermic needle lengths. Performance testing per ISO 9626:2016, ISO 7864:2016 verified the substantial equivalence of the new lengths.

Comment 2: The new needle gauges, specifically the 31G is within the established needle gauge range (23G-33G) for the Mini Needle product family. Performance testing per ISO 9626:2016, ISO 7864:2016, ISO 6009:2016 verified the substantial equivalence of the new gauges.

The performance test data demonstrating compliance with ISO 9626:2016- Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods, ISO 7864:2016- Sterile hypodermic needles for single use- Requirements and test methods and ISO 6009:2016- Hypodermic needles for single use- color coding for identification demonstrate that the additional needle configurations have no adverse effect on the established safety and performance characteristics of the device and demonstrate substantial equivalence.

The technological characteristics of the modified SteriCap Mini Needle and Needles are similar to the technological characteristics of the SteriCap Mini Needle previously cleared (K183016) version of the device. The fundamental difference is the additional needle lengths.

At a high level, the subject and predicate devices are based on the following same technological elements:

- all intended for use with a luer-tip syringe for the administration of drugs into the body
- All are fabricated from the same materials
- all have a lancet bevel tip configuration
- all SteriCap Mini Needles have a cap feature which functions as a contamination prevention feature from surrounding hairs/tissue during injection

The following technological differences exist between the subject and predicate devices:

Additional needle lengths have been incorporated into the product family, namely 4mm, 6mm, 8mm and 13mm

An additional needle gauge has been incorporated into the product family, namely 31G

VII. PERFORMANCE DATA

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

- Dimensional and Physical Properties Verification (ISO 9626:2016, ISO 7864:2016)
- Needle quality (ISO 9626:2016, ISO 7864:2016)
- Color coding (ISO 6009:2016, ISO 7864:2016)

Biocompatibility
In accordance with ISO 10993-1, the needle is classified as: Externally communicating Device, Blood Path Indirect, Limited contact (<24 hours). The previous testing performed, namely cytotoxicity, sensitization, irritation, acute systemic toxicity and materials mediated pyrogenicity remains applicable to the product family.

Sterility/Shipping and Shelf-life
The Mini Needle and Needles are sterilized using ethylene oxide. The sterilization cycle was validated based on the principles of ISO 11135:2014. The residual levels meet the requirements of ISO 10993-7 with EO $\leq$ 4mg and ECH $\leq$ 9mg. LAL testing for each lot of devices ensures the devices meet the acceptance criteria of < 20 EU/device.

The shelf-life was validated using industry-standard accelerated aging techniques (ASTM F1980-16), and assured functional performance of the device as well as packaging and sterile barrier integrity. The shelf-life validation included anticipated stress associated with transportation and handling, per ASTM D4169-16. Packaging integrity was validated using the bubble leak test method (ASTM F2096-11). The seal strength was verified per ASTM F88/F88M-15.

VIII. CONCLUSIONS

The subject device met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the additions to the SteriCap® Mini Needle and Needles were found to have a safety and effectiveness profile that is similar to the predicate device.