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

Re: K183016
Trade/Device Name: SteriCap Mini Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 15, 2019
Received: April 17, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah Mollo

for Tina Kiang, Ph.D
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183016

Device Name
SteriCap™ Needle

Indications for Use *(Describe)*
The SteriCap™ Needle is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K183016

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: April 8, 2019
Establishment Registration Number:3012478173

II. DEVICE
Name of the device: SteriCap™ Mini Needle
Common of usual name: Needle
Classification name: Single lumen hypodermic needle
Regulatory Class: 2
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

III. PREDICATE DEVICE
Mini-Needle (K170768)
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION
The SteriCap™ Mini Needle is a device intended to provide a means of fluid delivery into the human body via body surface puncture. The device is a single lumen needle available in sizes ranging from 23G – 33G. The distal end of the needle has a spring-loaded needle cap, which protects the needle prior to use.

V. INDICATIONS FOR USE
The SteriCap™ Mini Needle is 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

	SteriCap™ Mini Needle	**Mini Needle (K170768)- Primary Predicate**
Intended Use	The SteriCap™ Mini Needle is intended for use with a luer-tip syringe for the administration of drugs.	The Mini Needle is intended for use with a luer-tip syringe for the administration of drugs
Principle of Operation	SAME as K170768	Manual
Design/Construction	SAME as K170768	• Needle Assembly (cannula, needle hub, spring loaded needle cap) • Designed to fit standard 6% luer fittings
Materials	SAME as K170768	Cannula- Stainless steel Lubricant- Silicone Adhesive- polyacrylate Hub- polypropylene Needle Cap- polypropylene Spring- stainless steel
Needle Taper	SAME as K170768	None
Needle Length- total	SAME as K170768	20 mm
Needle length- projected	SAME as K170768	5.5mm
Needle Gauge	33G 32G 30G 29G 27G 25G 23G	33G 32G 30G
Tip Configuration	SAME as K170768	Lancet Bevel
Wall Type	SAME as K170768	Std wall
Sterilization	SAME as K170768	Ethylene oxide
How provided	SAME as K170768	Sterile, single use
Sterile barrier	SAME as K170768	Blister pouch

The technological characteristics of the modified SteriCap™ Mini Needle are similar to the technological characteristics of the SteriCap™ Mini Needle previously cleared (K170768) version of the device. The only difference is the additional needle gauges.

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 have a total needle length of 20mm with an exposed length of 5.5mm
- all have a lancet bevel tip configuration
- all 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 gauge diameters have been incorporated into the product family, namely 23G, 25G, 27G and 29G.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Needle Cap Sliding Force
- Twist Lock Release Force
- Dimensional and Physical Properties Verification (ISO 594-1 & 2)
  - Luer compatibiility
- Bond and Material Strength Verification (ISO 594-1 & 2; ISO 7864)
  - Needle cap bond strength
  - Needle to luer hub bond strength
- Needle quality (ISO 9626, ISO 7864)
  - Needle OD
  - Needle ID
  - Overall and Exposed Needle Length Verification
  - Needle stiffness
  - Bending-breakage resistance
  - Resistance to corrosion
  - Limits for acidity and alkalinity
  - Limits for extractable metals
  - Needle cleanliness
  - Coring
  - Needle point sharpness
  - Needle patency
- Color coding (ISO 6009, ISO 7864)

The product line extension met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the modified SteriCap™ Mini Needle was found to have a substantially equivalent safety and effectiveness profile to the predicate device.

VIII. CONCLUSIONS

Based on the comparison and analysis above the SteriCap™ Mini Needle is considered substantially equivalent to the legally marketed predicate devices.