DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 10, 2017

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

Re: K170768
Trade/Device Name: Mini Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 7, 2017
Received: June 8, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

James P. Bertram -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170768

Device Name
Mini Needle

Indications for Use *(Describe)*
The 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

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- K170768

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	OcuJect, LLC
DATE PREPARED:	July 6, 2017
CONTACT PERSON:	Rebecca K Pine 1441 Avocado Ave, Suite 204 Newport Beach, CA 92660 (760) 809-5178
TRADE NAME:	Mini Needle
COMMON NAME:	Needle
CLASSIFICATION NAME:	Hypodermic single lumen needle
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 880.5570
PRODUCT CODE	FMI
PREDICATE DEVICE:	Mini- Needle (K151571)

Reason for submission:
Modification to previously cleared device K151571.

Description of the Device Subject to Premarket Notification:
The 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 30G, 32G and 33G sizes with a 5.5mm exposed length. The distal end of the needle has a spring-loaded needle cap, which shields the needle prior to use.

Indication for Use:
The Mini Needle is intended for use with a luer-tip syringe (e.g. luer-lock or slip-tip luer syringe) for the administration of drug.

Technical Characteristics:
The Mini Needle has similar physical and technical characteristics to the predicate device, as shown in the table below.

	Mini Needle	**Mini Needle (K151571)**
Intended Use	The Mini Needle is intended for use with a	The Mini Needle is intended for use with a

	Mini Needle	**Mini Needle (K151571)**
	luer-tip syringe for the administration of drugs into the body.	luer-tip syringe for the administration of drugs into the body.
Principle of Operation	SAME	Manual
Design/Construction	• Needle Assembly (cannula, needle hub, spring loaded needle cap) • Designed to fit standard 6% luer fittings	• Needle Assembly (cannula, needle hub, needle cap, clip) • Designed to fit standard 6% luer fittings
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 with TPE tip, retaining ring Clip- polypropylene
Needle Taper	SAME	None
Needle Length- total	SAME	20 mm
Needle length- exposed	SAME	5.5mm
Needle Gauge	SAME	30G 32G 33G
Tip Configuration	SAME	Lancet Bevel
Wall Type	SAME	Std wall
Sterilization	Ethylene oxide	Irradiation
How provided	SAME	Sterile, single use

Each of the technical attributes of the Mini Needle are present in the predicate device. The materials, needle bevel and other fundamental design characteristics are all the same. The Needle Cap design has been modified from the predicate device, to incorporate a spring for ease of use. The incorporation of the spring feature eliminated the need for the Clip, as well as the retaining ring feature and TPE tip on the Needle Cap. These modifications have no effect on the fundamental operational characteristics of the device. The needle cap continues to function as a contamination prevention feature for the needle from surrounding tissues/hairs during injection. The primary sterile barrier is modified from a Tyvek pouch to a blister pouch. The sterilization method has been changed to exposure to ethylene oxide (EtO). EtO is well-known sterilization process common in the medical device industry

Performance Data:
All necessary testing has been performed for the Mini Needle to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Dimensional and Physical Properties Verification (ISO 594-1 & 2)
- Bond and Material Strength Verification (ISO 594-1 & 2)
- Biocompatibility Testing (ISO 10993-1; ISO 10993-7)
- Sterilization Validation (ISO 11135)
- Packaging Validation
    - Climatic Cycling & Transit Testing (ASTM D4169-16)
    - Pouch Seal Testing (ASTM 2069-11 and ASTM F88/F88M-15)

The Mini Needle met all specified criteria and did not raise different safety or performance questions.

Basis for Determination of Substantial Equivalence:

Conclusion
The Mini Needle has the same intended use, technological characteristics and performance and is substantially equivalent to the predicate device.