



Food and Drug Administration
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October 14, 2015

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

Re: K151571

Trade/Device Name: Mini Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 3, 2015
Received: September 4, 2015

Dear Ms. 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" (21CFR 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 yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151571

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.

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Section 6**510(k) Summary****6. 510(k) Summary**

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: October 14, 2015

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: Single lumen hypodermic needle

DEVICE CLASSIFICATION: Class 2, per 21 CFR 880.5570

PRODUCT CODE FMI

PREDICATE DEVICES: (primary) TSK Hypodermic Needle (K970370)

Substantially Equivalent To:

The Mini Needle is substantially equivalent in intended use, principal of operation and technological characteristics to the predicate devices identified above.

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. The distal end of the needle has a needle cap, which protects 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 drugs

Technical Characteristics:

The Mini Needle has similar physical and technical characteristics to the predicate devices, as shown in the table below.

	Mini Needle	TSK Hypodermic Needle
Intended Use	The Mini Needle is intended for use with a luer-tip syringe for the administration of drugs into the body.	The TSK Hypodermic needle is a single lumen needle intended to inject fluids into, or withdraw fluids from parts of the body below the surface of the skin.
Principle of Operation	Manual	Manual
Design/Construction	<ul style="list-style-type: none"> • Needle Assembly (cannula, needle hub, needle cap, clip) • Designed to fit standard 6% luer fittings 	<ul style="list-style-type: none"> • Needle Assembly (cannula, needle hub, protector cap) • Designed to fit standard 6% luer fittings
Materials	Cannula- Stainless steel Lubricant- Silicone Adhesive- polyacrylate Hub- polypropylene Needle Cap- polypropylene with TPE tip Clip- polypropylene	Cannula- Stainless steel Adhesive - epoxy Lubricant- Silicone Protector Cap- unknown Hub- polypropylene
Needle Taper	None	None
Needle Length	5.5mm	9mm 13mm
Needle Gauge	30G 32G 33G	14G to 31G
Tip Configuration	Lancet Bevel	Lancet Bevel
Wall Type	Std wall	Std wall
Sterilization	Irradiation	Irradiation
How provided	Sterile, single use	Sterile, Single Use

Each of the technical attributes of the Mini Needle are present in the predicate devices. The materials, needle bevel and other fundamental design characteristics are all the same. The slightly smaller needle gauge of the Mini Needle has no effect on the fundamental operational characteristics of the device. The effective length of the Mini Needle is within the established lengths of the predicate device. The Mini Needle has a sliding needle cap

to prevent needle contamination from surrounding tissues/hairs during injection. This element is an augmentation to the overall design and has no effect on the fundamental design of the device. The Mini Needle is indicated for the delivery of drugs into the human body, whereas the TSK Needle is indicated for the delivery and withdrawal of fluids into and from the human body. This difference does not affect the substantial equivalence of the device, as the Mini Needle indications are merely more specific regarding the type of fluid and more precise based on the design of the device.

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)
- Sterilization Validation (ISO 11137-1/2)
- Packaging Validation

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

Basis for Determination of Substantial Equivalence:*Conclusion*

Upon reviewing the information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Mini Needle is substantially equivalent to the predicate device.