



November 27, 2023

OcuJect, LLC  
% Heidi Busz  
Senior Regulatory Consultant  
Namsa  
400 Highway 169 South Suite 500  
Minneapolis, Minnesota 55426

Re: K233343

Trade/Device Name: SteriCap Safety Needle; VitreJect Safety Needle  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: Class II  
Product Code: FMI  
Dated: September 29, 2023  
Received: September 29, 2023

Dear Heidi Busz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Juliane C. Lessard -S**

Juliane C. Lessard, 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

## Indications for Use

510(k) Number (if known)

K233343

Device Name

SteriCap Safety Needle;

VitreJect Safety Needle

### Indications for Use (Describe)

The SteriCap Safety Needle is intended for use with a luer-tip syringe for the administration of drugs.

The SteriCap Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick.

The VitreJect Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect Safety Needle is indicated for intravitreal use.

The VitreJect Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick.

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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**K233343 510(k) Summary**

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**I. SUBMITTER**

OcuJect, LLC

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Newport Beach, CA 92660

Phone: (949) 721-6716

Email: [llerner@ocuject.com](mailto:llerner@ocuject.com)

Primary Contact: Leonid Lerner, MD, PhD

Date prepared: October 16, 2023

**II. DEVICE**

Device Name: SteriCap<sup>®</sup> Safety Needle and VitreJect<sup>®</sup> Safety Needle

Common/Usual Name: Hypodermic needle with safety system

Classification Name: Needle, Hypodermic, Single Lumen (21 CFR 880.5570)

Regulatory Class: II

Product Code: FMI

**III. PREDICATE DEVICE**

SteriCap<sup>®</sup> Mini Needle, K212805 | VitreJect<sup>®</sup> Needle, K230959

The predicate devices have not been subject to design-related recall.

**IV. DEVICE DESCRIPTION****SteriCap Safety Needle**

The SteriCap Safety Needle is designed to provide a means of fluid injection and aspiration to and from the body. It is a single lumen hypodermic needle intended for use with a luer-tip syringe. The SteriCap Safety Needle has a spring-actuated, non-removable sliding cap that moves along the axis of the needle hub during clinical use and automatically re-covers the needle tip after use. The needle cap can be manually locked/unlocked. The SteriCap Safety Needle is intended for manual use by health care professionals for administration of drugs. The SteriCap Safety Needle is single use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas.

**VitreJect Safety Needle**

The VitreJect Safety Needle is designed to provide a means of fluid injection and aspiration to and from the body. It is a single lumen hypodermic needle intended for use with a luer-tip syringe. The VitreJect Safety Needle has a spring-actuated, non-removable sliding cap that moves along the axis of the needle hub during clinical use and automatically re-covers the needle tip after use. The needle cap can be manually locked/unlocked. The VitreJect Safety Needle is intended for manual use by health care professionals for administration of drugs. The VitreJect Safety Needle is single

use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas. The VitreJect Safety Needle is suitable for ophthalmic use.

## V. INTENDED USE / INDICATIONS FOR USE

### SteriCap Safety Needle

The SteriCap Safety Needle is intended for use with a luer-tip syringe for the administration of drugs.

The SteriCap Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick.

### VitreJect Safety Needle

The VitreJect Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect Safety Needle is indicated for intravitreal use.

The VitreJect Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the SteriCap Safety Needle and VitreJect Safety Needle are substantially equivalent to the predicate devices. The intended use of the subject devices is identical to the predicate devices.

|                                                  | Intended Use                                                       | Indications for Use                                                                                                                                                                                                                                                                                                                                                                                                                       | Discussion                                                                                                                                                                                              | Associated Testing Standard                                                |
|--------------------------------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <b>Subject Device<br/>SteriCap Safety Needle</b> | <b>SteriCap Safety Needle</b>                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                         |                                                                            |
|                                                  | Intended to inject fluids into, or withdraw fluids from, the body. | The SteriCap Safety Needle is intended for use with a luer-tip syringe for the administration of drugs.<br>The SteriCap Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick. | Identical intended use supported by referenced performance and biocompatibility testing.<br><br>Equivalent indications for use. The existing integrated mechanism of the predicate SteriCap Mini Needle | ISO 7864, Internal Standards, ISO 23908, ISO 80369-7, ISO 10993, USP <788> |

|                                                        |                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                           |                                                                                       |
|--------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Predicate Device SteriCap Mini Needle (K212805)</b> | Intended to inject fluids into, or withdraw fluids from, the body. | The SteriCap Mini Needle is intended for use with a luer-tip syringe for the administration of drugs.                                                                                                                                                                                                                                                                                                                                    | is not indicated as sharps injury prevention feature.                                                                                                                                                                                                     |                                                                                       |
| <b>Subject Device VitreJect Safety Needle</b>          | <b>VitreJect Safety Needle</b>                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                           |                                                                                       |
|                                                        | Intended to inject fluids into, or withdraw fluids from, the body. | The VitreJect Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect Safety Needle has an integrated passive needle shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle shield. The locked needle shield minimizes risk of accidental needle stick. | Identical intended use supported by referenced performance and biocompatibility testing.<br><br>Equivalent indications for use. The existing integrated mechanism of the predicate VitreJect Needle is not indicated as sharps injury prevention feature. | ISO 7864, Internal Standards, ISO 23908, ISO 80369-7, ISO 10993, USP <788>, USP <789> |
| <b>Predicate Device VitreJect Needle (K230959)</b>     | Intended to inject fluids into, or withdraw fluids from, the body. | The VitreJect Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect Needle is indicated for intravitreal use.                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                           |                                                                                       |

The SteriCap Safety Needle has identical technological characteristics when compared to predicate SteriCap Mini Needle. These devices have identical design, material, manufacturing process, sterilization method, operation method, and packaging configuration; however, the SteriCap Mini Needle does not indicate the integrated sliding needle cap and locking mechanism as a safety feature.

The VitreJect Safety Needle has identical technological characteristics when compared to predicate VitreJect Needle. These devices have identical design, material, manufacturing process, sterilization method, operation method, and packaging configuration; however, the VitreJect Needle does not indicate the integrated sliding needle cap and locking mechanism as a safety feature.

Comparisons of the technological characteristics between the subject and predicate devices are illustrated in the tables below:

| <b>SteriCap Safety Needle</b> |                                              |                                                        |                   |                                    |
|-------------------------------|----------------------------------------------|--------------------------------------------------------|-------------------|------------------------------------|
| <b>Characteristic</b>         | <b>Subject Device SteriCap Safety Needle</b> | <b>Predicate Device SteriCap Mini Needle (K212805)</b> | <b>Discussion</b> | <b>Associated Testing Standard</b> |
| Applicant                     | OcuJect, LLC                                 | Identical                                              |                   |                                    |
| Proprietary Name              | SteriCap                                     | Identical                                              |                   |                                    |

| SteriCap Safety Needle            |               |                                                                                                                            |                                                             |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|-----------------------------------|---------------|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Characteristic                    |               | Subject Device<br>SteriCap Safety<br>Needle                                                                                | Predicate<br>Device<br>SteriCap Mini<br>Needle<br>(K212805) | Discussion                                                                                                                                                       | Associated<br>Testing<br>Standard                                                                                                                                                                                     |
| Device                            |               | Needle,<br>Hypodermic,<br>Single Lumen                                                                                     | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Regulation Number                 |               | 21 CFR 880.5570                                                                                                            | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Product Code                      |               | FMI                                                                                                                        | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Device Class                      |               | II                                                                                                                         | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Regulation Medical<br>Specialty   |               | General Hospital                                                                                                           | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Intended Users and<br>Environment |               | Clinicians in a<br>clinical setting.                                                                                       | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Principle of<br>Operation         |               | Connects to a luer<br>type syringe to<br>serve as a conduit<br>for the movement<br>of fluid.                               | Identical                                                   |                                                                                                                                                                  | ISO 7864,<br>ISO 9626,<br>ISO 80369-7                                                                                                                                                                                 |
| Device Components                 |               | Needle Assembly:<br>needle, needle hub,<br>spring-loaded<br>needle cap)<br>Designed to fit<br>standard 6% luer<br>fittings | Identical                                                   |                                                                                                                                                                  | ISO 10993-<br>1,<br>ISO 10993-<br>5, ISO<br>10993-7,<br>ISO 10993-<br>10,<br>ISO 10993-<br>11,<br>ISO 10993-<br>12,<br>ISO 7864,<br>ISO 9626,<br>ISO 6009,<br>ISO 80369-<br>7,<br>Internal<br>Standards,<br>ISO 23908 |
| Material                          | Needle        | Stainless steel                                                                                                            | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|                                   | Needle<br>hub | Polypropylene                                                                                                              | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|                                   | Lubricant     | Silicone                                                                                                                   | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|                                   | Spring        | Stainless steel                                                                                                            | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|                                   | Adhesive      | Polyacrylate                                                                                                               | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
|                                   | Needle<br>cap | Polypropylene                                                                                                              | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Needle Length<br>(Exposed)        |               | 4 mm, 5.5 mm, 6<br>mm                                                                                                      | Identical                                                   |                                                                                                                                                                  | ISO 7864,<br>ISO 9626                                                                                                                                                                                                 |
| Needle Length<br>(Total)          |               | 19.5 mm, 20 mm,<br>21.5 mm                                                                                                 | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Needle Tip                        |               | Lancet Bevel                                                                                                               | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Needle Taper                      |               | None                                                                                                                       | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Wall Type                         |               | Std                                                                                                                        | Identical                                                   |                                                                                                                                                                  |                                                                                                                                                                                                                       |
| Needle Gauge                      |               | 30G,31G,33G                                                                                                                | 23G,25G,27G,<br>29G,30G,31G,<br>32G,33G                     | Differences in configuration /<br>size offering do not raise new or<br>different questions of safety or<br>effectiveness. All claim<br>conformance to standards. | ISO 7864,<br>ISO 9626,<br>ISO 6009                                                                                                                                                                                    |
| Configurations                    |               | 31G x 4 mm<br>33G x 4 mm                                                                                                   | 31G x 4 mm<br>33G x 4 mm                                    |                                                                                                                                                                  |                                                                                                                                                                                                                       |

| SteriCap Safety Needle                                                                                                                                                             |                                                                                                                                                                                      |                                                                                                                                                        |            |                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Characteristic                                                                                                                                                                     | Subject Device<br>SteriCap Safety<br>Needle                                                                                                                                          | Predicate<br>Device<br>SteriCap Mini<br>Needle<br>(K212805)                                                                                            | Discussion | Associated<br>Testing<br>Standard                                                                                                                                                                                                   |
|                                                                                                                                                                                    | 30G x 5.5 mm<br>31G x 5.5 mm<br>33G x 5.5 mm<br>30G x 6 mm<br>31G x 6 mm<br>33G x 6 mm                                                                                               | 23G x 5.5 mm<br>25G x 5.5 mm<br>27G x 5.5 mm<br>29G x 5.5 mm<br>30G x 5.5 mm<br>32G x 5.5 mm<br>33G x 5.5 mm<br>30G x 6 mm<br>31G x 6 mm<br>33G x 6 mm |            |                                                                                                                                                                                                                                     |
| Connection                                                                                                                                                                         | Luer-slip<br>Luer-lock                                                                                                                                                               | Identical                                                                                                                                              |            | ISO 7864,<br>ISO 80369-7                                                                                                                                                                                                            |
| Needle Color<br>Coding                                                                                                                                                             | Conforms to ISO<br>6009                                                                                                                                                              | Identical                                                                                                                                              |            | ISO 6009                                                                                                                                                                                                                            |
| Sterilization and<br>Shelf Life                                                                                                                                                    | Provided Sterile,<br>Single-Use<br>100 individual<br>blister packed<br>devices packaged<br>into shelf carton<br>Sterilization<br>Method: EO<br>SAL: $10^{-6}$<br>Shelf Life: 5 years | Identical                                                                                                                                              |            | AAMI<br>TIR28,<br>ISO 11135,<br>ISO 10993-<br>7,<br>USP <85>,<br>USP <161>,<br>ANSI/AAMI<br>ST72,<br>ASTM<br>F1980-16,<br>ISO 7864,<br>ISO 9626,<br>ISO 80369-<br>7,<br>ISO 11607-<br>1,<br>ASTM<br>F88/F88-15,<br>ASTM<br>D4169-16 |
| Biocompatibility per<br>ISO 10993-1;<br>categorization as<br>externally<br>communicating<br>device with limited<br>(<24 hours) direct<br>tissue and indirect<br>blood path contact | Non-cytotoxic                                                                                                                                                                        | Identical                                                                                                                                              |            | ISO 10993-5                                                                                                                                                                                                                         |
|                                                                                                                                                                                    | Non-sensitizer                                                                                                                                                                       | Identical                                                                                                                                              |            | ISO 10993-<br>10                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-irritant,<br>Intracutaneous<br>Reactivity                                                                                                                                        | Identical                                                                                                                                              |            | ISO 10993-<br>10                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-pyrogenic                                                                                                                                                                        | Identical                                                                                                                                              |            | ISO 10993-<br>11,<br>USP <151>                                                                                                                                                                                                      |
|                                                                                                                                                                                    | Non-toxic                                                                                                                                                                            | Identical                                                                                                                                              |            | ISO 10993-<br>11                                                                                                                                                                                                                    |

| SteriCap Safety Needle |                                                                                                   |                                                                                                |                                                                                                                                                       |                                   |
|------------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Characteristic         | Subject Device<br>SteriCap Safety<br>Needle                                                       | Predicate<br>Device<br>SteriCap Mini<br>Needle<br>(K212805)                                    | Discussion                                                                                                                                            | Associated<br>Testing<br>Standard |
| Performance Data       | Needle performance meets design specification and conforms to standard.                           | Identical                                                                                      |                                                                                                                                                       | ISO 7864,<br>ISO 9626             |
|                        | Luer connection performance meets design specification and conforms to standard.                  | Identical                                                                                      |                                                                                                                                                       | ISO 80369-7                       |
|                        | Particulates meet design specification and conforms to standard.                                  | Identical                                                                                      |                                                                                                                                                       | USP <788>                         |
|                        | Sharps Injury Prevention Feature performance meets design specification and conforms to standard. | N/A<br>The existing integrated mechanism is not indicated as sharps injury prevention feature. | Passed bench testing for sharps injury prevention feature activation, access in the safe mode, and destructive force, and demonstrate 0% injury rate. | Internal Standards,<br>ISO 23908  |

| VitreJect Safety Needle        |                                              |                                                         |            |                                   |
|--------------------------------|----------------------------------------------|---------------------------------------------------------|------------|-----------------------------------|
| Characteristic                 | Subject Device<br>VitreJect Safety<br>Needle | Predicate<br>Device<br>VitreJect<br>Needle<br>(K230959) | Discussion | Associated<br>Testing<br>Standard |
| Applicant                      | OcuJect, LLC                                 | Identical                                               |            |                                   |
| Proprietary Name               | VitreJect                                    | Identical                                               |            |                                   |
| Device                         | Needle,<br>Hypodermic,<br>Single Lumen       | Identical                                               |            |                                   |
| Regulation Number              | 21 CFR 880.5570                              | Identical                                               |            |                                   |
| Product Code                   | FMI                                          | Identical                                               |            |                                   |
| Device Class                   | II                                           | Identical                                               |            |                                   |
| Regulation Medical Specialty   | General Hospital                             | Identical                                               |            |                                   |
| Intended Users and Environment | Clinicians in a clinical setting.            | Identical                                               |            |                                   |

| VitreJect Safety Needle |            |                                                                                                             |                                                         |            |                                                                                                                                  |
|-------------------------|------------|-------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|------------|----------------------------------------------------------------------------------------------------------------------------------|
| Characteristic          |            | Subject Device<br>VitreJect Safety<br>Needle                                                                | Predicate<br>Device<br>VitreJect<br>Needle<br>(K230959) | Discussion | Associated<br>Testing<br>Standard                                                                                                |
| Principle of Operation  |            | Connects to a luer type syringe to serve as a conduit for the movement of fluid.                            | Identical                                               |            | ISO 7864, ISO 9626, ISO 80369-7                                                                                                  |
| Device Components       |            | Needle Assembly: needle, needle hub, spring-loaded needle cap)<br>Designed to fit standard 6% luer fittings | Identical                                               |            | ISO 10993-1, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-23, USP <151>, ISO 10993-4, ASTM F756 |
| Material                | Needle     | Stainless steel                                                                                             | Identical                                               |            | ISO 7864, ISO 9626, ISO 6009, ISO 80369-7, Internal Standards, ISO 23908                                                         |
|                         | Needle hub | Polypropylene                                                                                               | Identical                                               |            |                                                                                                                                  |
|                         | Lubricant  | Silicone                                                                                                    | Identical                                               |            |                                                                                                                                  |
|                         | Spring     | Stainless steel                                                                                             | Identical                                               |            |                                                                                                                                  |
|                         | Adhesive   | Polyacrylate                                                                                                | Identical                                               |            |                                                                                                                                  |
|                         | Needle cap | Polypropylene                                                                                               | Identical                                               |            |                                                                                                                                  |
| Needle Length (Exposed) |            | 4 mm, 5.5 mm, 6 mm                                                                                          | Identical                                               |            | ISO 7864, ISO 9626                                                                                                               |
| Needle Length (Total)   |            | 19.5 mm, 20 mm, 21.5 mm                                                                                     | Identical                                               |            |                                                                                                                                  |
| Needle Tip              |            | Lancet Bevel                                                                                                | Identical                                               |            |                                                                                                                                  |
| Needle Taper            |            | None                                                                                                        | Identical                                               |            |                                                                                                                                  |
| Wall Type               |            | Std                                                                                                         | Identical                                               |            |                                                                                                                                  |
| Needle Gauge            |            | 30G, 31G, 33G                                                                                               | Identical                                               |            | ISO 7864, ISO 9626, ISO 6009                                                                                                     |
| Configurations          |            | 31G x 4 mm<br>33G x 4 mm<br>30G x 5.5 mm<br>31G x 5.5 mm<br>33G x 5.5 mm<br>30G x 6 mm<br>31G x 6 mm        | Identical                                               |            | ISO 7864, ISO 9626, ISO 6009                                                                                                     |

| VitreJect Safety Needle                                                                                                                                                            |                                                                                                                                                                                             |                                                         |            |                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Characteristic                                                                                                                                                                     | Subject Device<br>VitreJect Safety<br>Needle                                                                                                                                                | Predicate<br>Device<br>VitreJect<br>Needle<br>(K230959) | Discussion | Associated<br>Testing<br>Standard                                                                                                                                                                                                   |
|                                                                                                                                                                                    | 33G x 6 mm                                                                                                                                                                                  |                                                         |            |                                                                                                                                                                                                                                     |
| Connection                                                                                                                                                                         | Luer-slip<br>Luer-lock                                                                                                                                                                      | Identical                                               |            | ISO 7864,<br>ISO 80369-7                                                                                                                                                                                                            |
| Needle Color<br>Coding                                                                                                                                                             | Conforms to ISO<br>6009                                                                                                                                                                     | Identical                                               |            | ISO 6009                                                                                                                                                                                                                            |
| Sterilization and<br>Shelf Life                                                                                                                                                    | Provided Sterile,<br>Single-Use<br>100 individual<br>blister packed<br>devices packaged<br>into shelf carton<br>Sterilization<br>Method: EO<br>SAL: 10 <sup>-6</sup><br>Shelf Life: 5 years | Identical                                               |            | AAMI<br>TIR28,<br>ISO 11135,<br>ISO 10993-<br>7,<br>USP <85>,<br>USP <161>,<br>ANSI/AAMI<br>ST72,<br>ASTM<br>F1980-16,<br>ISO 7864,<br>ISO 9626,<br>ISO 80369-<br>7,<br>ISO 11607-<br>1,<br>ASTM<br>F88/F88-15,<br>ASTM<br>D4169-16 |
| Biocompatibility per<br>ISO 10993-1;<br>categorization as<br>externally<br>communicating<br>device with limited<br>(<24 hours) direct<br>tissue and indirect<br>blood path contact | Non-cytotoxic                                                                                                                                                                               | Identical                                               |            | ISO 10993-5                                                                                                                                                                                                                         |
|                                                                                                                                                                                    | Non-sensitizer                                                                                                                                                                              | Identical                                               |            | ISO 10993-<br>10                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-irritant,<br>Intracutaneous<br>Reactivity                                                                                                                                               | Identical                                               |            | ISO 10993-<br>10                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-pyrogenic                                                                                                                                                                               | Identical                                               |            | ISO 10993-<br>11,<br>USP <151>                                                                                                                                                                                                      |
|                                                                                                                                                                                    | Non-toxic                                                                                                                                                                                   | Identical                                               |            | ISO 10993-<br>11                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-hemolytic                                                                                                                                                                               | Identical                                               |            | ISO 10993-<br>4, ASTM<br>F756                                                                                                                                                                                                       |
|                                                                                                                                                                                    | Non-irritant,<br>Ocular                                                                                                                                                                     | Identical                                               |            | ISO 10993-<br>10                                                                                                                                                                                                                    |
|                                                                                                                                                                                    | Non-irritant,<br>Intravitreal<br>Injection                                                                                                                                                  | Identical                                               |            | ISO 13485                                                                                                                                                                                                                           |

| VitreJect Safety Needle |                                                                                                                  |                                                                                                                  |                                                                                                                                                                   |                                     |
|-------------------------|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Characteristic          | Subject Device<br>VitreJect Safety<br>Needle                                                                     | Predicate<br>Device<br>VitreJect<br>Needle<br>(K230959)                                                          | Discussion                                                                                                                                                        | Associated<br>Testing<br>Standard   |
|                         | Non-irritant,<br>Intraocular                                                                                     | Identical                                                                                                        |                                                                                                                                                                   | ISO 13485                           |
| Performance Data        | Needle<br>performance meets<br>design specification<br>and conforms to<br>standard.                              | Identical                                                                                                        |                                                                                                                                                                   | ISO 7864,<br>ISO 9626               |
|                         | Luer connection<br>performance meets<br>design specification<br>and conforms to<br>standard.                     | Identical                                                                                                        |                                                                                                                                                                   | ISO 80369-7                         |
|                         | Particulates meet<br>design specification<br>and conforms to<br>standard.                                        | Identical                                                                                                        |                                                                                                                                                                   | USP <788><br>USP <789>              |
|                         | Sharps Injury<br>Prevention Feature<br>performance meets<br>design specification<br>and conforms to<br>standard. | N/A<br>The existing<br>integrated<br>mechanism is<br>not indicated as<br>sharps injury<br>prevention<br>feature. | Passed bench testing for sharps<br>injury prevention feature<br>activation, access in the safe<br>mode, and destructive force, and<br>demonstrate 0% injury rate. | Internal<br>Standards,<br>ISO 23908 |

## VII. PERFORMANCE DATA

### SteriCap Safety Needle

The following non-clinical testing was performed to confirm the safety and effectiveness of the SteriCap Safety Needle as compared to the predicate device. Performance testing was performed as per the design control system. The following tests were conducted:

- Dimensional and Physical Properties Verification
  - ISO 7864, ISO 80369-7
- Bond and Material Strength Verification
  - ISO 7864, ISO 80369-7
- Needle quality
  - ISO 9626, ISO 7864
- Color coding
  - ISO 6009, ISO 7864
- Luer connector
  - ISO 80369-7
- Particulate testing

- USP <788>
- Sharps Injury Prevention Feature
  - Internal Standards
  - ISO 23908
- Biocompatibility (ISO 10993-1)

SteriCap Safety Needle is categorized as an externally communicating device with limited (<24 hours) direct tissue and indirect blood path contact. The testing performed remains applicable to the SteriCap/VitreJect product family and demonstrates the subject device is biocompatible for its intended use.
- Sterility and Shelf Life

SteriCap Safety Needle is 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. LAL testing for each lot ensures the devices meet the acceptance criteria of 20 EU/device.

Shelf-life was validated using industry-standard accelerated aging technique (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.

#### VitreJect Safety Needle

The following non-clinical testing was performed to confirm the safety and effectiveness of the VitreJect Safety Needle as compared to the predicate device. Performance testing was performed as per the design control system. The following tests were conducted:

- Dimensional and Physical Properties Verification
  - ISO 7864, ISO 80369-7
- Bond and Material Strength Verification
  - ISO 7864, ISO 80369-7
- Needle quality
  - ISO 9626, ISO 7864
- Color coding
  - ISO 6009, ISO 7864
- Luer connector
  - ISO 80369-7
- Particulate testing
  - USP <788>, USP <789>
- Sharps Injury Prevention Feature
  - Internal Standards
  - ISO 23908
- Biocompatibility (ISO 10993-1)

VitreJect Safety Needle is categorized as an externally communicating device with limited

(<24 hours) direct tissue and indirect blood path contact. The testing performed remains applicable to the SteriCap/VitreJect product family and demonstrates the subject device is biocompatible for its intended use.

- Sterility and Shelf Life

VitreJect Safety Needle is 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. LAL testing for each lot ensures the devices meet the acceptance criteria of  $\leq 0.2$  EU/device.

Shelf-life was validated using industry-standard accelerated aging technique (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. SUBSTANTIAL EQUIVALENCE

### SteriCap/VitreJect Safety Needle

The SteriCap/VitreJect Safety Needle are substantially equivalent to the predicate devices when evaluating intended use and technological characteristics.

- The subject devices have the identical intended use as the predicate devices.
- The subject devices specifically indicate a sharps injury prevention feature while the predicate devices do not indicate the existing integrated sliding needle cap and locking mechanism as a safety feature.
- The subject devices and predicate devices are identical in device materials, dimensional specifications, connection type, sterilization, packaging configuration, etc.
- Performance testing according to internal standards and ISO 23908 demonstrate the subject devices, specifically the sharps injury prevention feature, are as safe and effective as the legally marketed predicate devices and do not raise new or different questions of safety and effectiveness compared to the predicate devices.

The performance test data and post-market data recording a 0% injury rate demonstrate that the SteriCap Safety Needle and VitreJect Safety Needle meet the established safety and performance characteristics of the device and demonstrate substantial equivalence to the predicate devices.

## IX. CONCLUSIONS

The SteriCap Safety Needle and VitreJect Safety Needle meet the established safety and performance characteristics for a hypodermic injection needle with a safety/antistick system. Performance testing demonstrates the SteriCap Safety Needle and VitreJect Safety Needle are as safe and effective as the predicate devices and will perform as intended.

The SteriCap Safety Needle and VitreJect Safety Needle are biocompatible for their intended uses and demonstrate equivalent performance to their predicate devices. The SteriCap Safety Needle is



substantially equivalent to predicate SteriCap Mini Needle cleared under K212805. The VitreJect Safety Needle is substantially equivalent to predicate VitreJect Needle cleared under K230959.