DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2017

Procedure Products, Inc.
Mr. Doug Rowley
QA Manager
1801 W. 4th Plain Blvd.
Vancouver, Washington 98660

Re: K161812
Trade/Device Name: Freedom™ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 17, 2017
Received: February 21, 2017

Dear Mr. Doug Rowley:

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,


Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Change Control Table, Change History

### Change Control Table

| Version | Document Author | Document Approver | Date Approved |
|---|---|---|---|
| 1.00 | Name, Title, Office | Name, Title, Office | MM/DD/YYYY |

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K161812

Device Name
Freedom™ Syringe

Indications for Use *(Describe)*

The Freedom™ Syringe is intended to inject fluids into, or withdraw fluids from, the body.

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

510(k) Number: K161812

## General Provisions

Submitter's Name: Procedure Products, Inc.

Address: 1801 W 4th Plain Blvd.
Vancouver, WA 98660

Telephone Number: (360) 693-1832 or (888) 532-3396

Fax Number: (360) 690-4473

Contact Person: Doug Rowley
(360) 693-1832

Date of Preparation: 03/09/2017

## Subject Device

Trade Name: Freedom™ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Classification Panel: General Hospital

## Predicate Device

Trade Name: DMC Medical Single-Use Polycarbonate Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Classification Panel: General Hospital
Premarket Notification #: K103736

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## Indications for Use

The Freedom™ Syringe is intended to inject fluids into, or withdraw fluids from, the body.

## Device Description

The Freedom™ Syringe is a single-use medical device consisting of a calibrated hollow barrel and movable plunger (piston). The plunger contains a rubber stopper on the end that is positioned within the syringe barrel. A small amount of medical-grade silicone is used as a lubricant. The lubricant, stopper on the end of the plunger, and the syringe barrel are the components which make contact with the fluid path of the device. The syringe barrel contains a standard male luer lock connector that is compatible with standard female luer hubs. Freedom™ Syringes have a nominal capacity of 10ml, and are available sterile or non-sterile for further processing. The syringe is available in 5 different plunger colors: white, blue, red, yellow, or green.

## Principles of Operation

Freedom™ Syringes are manually operated by the user through the advancement and/or withdrawal of the syringe plunger within the barrel. Syringe content volume is measured by the user through the printed scale on the outside of the syringe barrel. These operating principles are identical to that of the predicate device and the vast majority of piston syringes currently on the market.

## Comparison to Predicate Device

The indications for use, technological characteristics, and principles of operation of the Freedom™ Syringe are substantially equivalent to those of the DMC Medical Single-Use Polycarbonate Syringe product line (predicate device). Both devices have been designed and tested to ensure compliance with the same set of consensus standards. The table on the following page provides additional comparison between the subject device (Freedom™ Syringe) and the predicate device (the DMC Medical Single-Use Polycarbonate Syringe).

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| Component / Characteristic | DMC Medical Single-Use Polycarbonate Syringe (Predicate Device) | Freedom™ Syringe (Subject Device) |
|---|---|---|
| Barrel | Polycarbonate | Triton® MX731 Copolyester |
| Plunger | ABS | ABS |
| Stopper | Elastomer | Polyisoprene Elastomer |
| Lubricant | Medical Grade Silicone | Medical Grade Silicone |
| Sterilization Method *(when applicable)* | Ethylene Oxide (EtO) | Ethylene Oxide (EtO) |
| Syringe Size(s) (nominal capacity) | Various, including 10ml | 10ml |
| ISO 10993-1 Compliance | Yes | Yes |
| ISO 7886-1 Compliance | Yes | Yes |
| ISO 594-1 & 594-2 Compliance | Yes | Yes |
| FDA 510(k) Numbers | K103736 | K161812 |
| Intended Use / Indications for Use | DMC Medical piston type syringes are single use syringes, intended for injecting fluids into or withdrawing fluids from the body. | The Freedom™ Syringe is intended to inject fluids into, or withdraw fluids from, the body. |
| Commentary regarding Indications for Use | As seen within the row above, the Indications for Use for the predicate device are not identical to the Indications for Use of the Freedom™ Syringe. However, the Freedom™ Syringe is a piston type, single use syringe, and as such the differences between the two Indications for Use are not considered to impact substantial equivalence. | |

## Technological Differences between Predicate and Subject Device

The only known technological difference between the Freedom™ Syringe and the predicate device is the differing materials that make up the syringe barrel (as noted in the table above). The Copolyester material utilized in the Freedom™ Syringe has been tested according to all applicable standards and found to be equivalent to the polycarbonate syringe barrel used by the predicate device with respect to function and compliance with these standards.

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## Non-Clinical Testing

Freedom™ Syringes have been tested to ensure conformance to all applicable performance requirements within the following standards:

| Standard Number | Standard Title |
|---|---|
| ISO 7886-1 | *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use* |
| ISO 594-1 | *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements* |
| ISO 594-2 | *ISO 594-2; Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings* |
| ISO 11135-1 | *Sterilization of health-care products – ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices* |
| ISO 10993-1 | *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* |
| ISO 10993-4 | *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood* |
| ISO 10993-5 | *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* |
| ISO 10993-7 | *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* |
| ISO 10993-10 | *Biological evaluation of medical devices - Part 10, Tests for Irritation and Skin Sensitization* |
| ISO 10993-11 | *Biological evaluation of medical devices – Part 11, Tests for systemic toxicity* |
| ANSI/AAMI ST72 | *Bacterial endotoxin -Test methods, routine monitoring and alternatives to batch testing* |

## Conclusions Drawn

Based on the indications for use, technological characteristics, testing performed and principles of operation, the Freedom™ Syringe meets all identified requirements and is considered to be substantially equivalent to the predicate device.