April 18, 2025

CarrTech Corp
℅ Ann Metz
Regulatory Affairs Specialist
Gilero
4319 S. Alston Ave
Durham, North Carolina 27713

Re: K240355
Trade/Device Name: FROG (Filter Removal of Glass)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 11, 2025
Received: April 11, 2025

Dear Ann Metz:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240355

Device Name

FROG (Filter Removal of Glass)

Indications for Use *(Describe)*

•The FROG device is a hypodermic needle and filter combination intended for use with syringes for general purpose fluid injection/aspiration and filtering.
•The FROG removable filter allows the device to first withdraw medications from glass ampules and filter out glass fragments prior to subsequent administration after the removal of the filter cover.
•The FROG device is intended to be used by health care practitioners supporting medical care of any patient where delivery of drug housed in a glass primary container (where there is potential for glass particulate to get into drug upon opening of said primary container) is required.

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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K240355 - 510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92.

I. Submitter

Submitter's Name:	CarrTech Corp
Contact Person:	Sue Carr President
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Date Preparation:	April 17, 2025

II. Application Correspondent

Contact's Name:	Gilero, LLC
Contact Person:	Ann Metz Regulatory Affairs Specialist
Address:	4319 S Alston Ave Durham, NC 27713
Telephone:	(984) 204-4460
Email:	ametz@gilero.com

III. Subject Device

Trade Name:	FROG (Filter Removal of Glass)
Common Name:	Needle, Hypodermic, Single Lumen
Classification Name:	Hypodermic single lumen needle
Product Classification:	Class II
Regulation Number:	21 CFR 880.5570
Product Code:	FMI

IV. Predicate Device

Manufacturer:	BD
Device Name:	BD Precision Glide Needle
510(k) Number:	K021475
Product Classification:	Class II
Product Code:	FMI
Regulation Number:	21 CFR 880.5570

V. Device Description

The FROG device is a prescription device intended for use by healthcare professionals in a healthcare or outpatient setting. The FROG device incorporates a removable filter, which surrounds the hypodermic needle and allows the filtered aspiration of glass-contaminated drug into the syringe. After aspiration, the filter is removed from the device, permitting injection with the hypodermic needle which is already attached to the syringe. Each package will include an assembled FROG device. The device is intended for single use and provided sterile.

VI. Indications for Use

- The FROG device is a hypodermic needle and filter combination intended for use with syringes for general purpose fluid injection/aspiration and filtering.
- The FROG removable filter allows the device to first withdraw medications from glass ampules and filter out glass fragments prior to subsequent administration after the removal of the filter cover.
- The FROG device is intended to be used by health care practitioners supporting medical care of any patient where delivery of drug housed in a glass primary container (where there is potential for glass particulate to get into drug upon opening of said primary container) is required.

VII. Comparison of Technological Characteristics with the Predicate Devices

The following table (5-1) contains a comparison of the technological characteristics of the subject device (FROG (Filter Removal of Glass)) and the predicate device (BD Precision Glide Needle). Along with the comparison, the table contains an analysis of the equivalency between the subject and predicate devices. The reference device is listed as a reference device for methods to evaluate the filtering capability.

Table 5-1: General Technological Characteristics Comparison

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Device Class	Class II	Class II	Subject and Predicate devices - Equivalent
Device Classification Name	Needle, Hypodermic, Single Lumen	Needle, Hypodermic, Single Lumen	Subject and Predicate devices - Equivalent
Regulation Number	880.5570	880.5570	Subject and Predicate devices - Equivalent
Product Code	FMI	FMI	Subject and Predicate devices - Equivalent

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Indications for Use and Intended Use	The FROG device is a hypodermic needle and filter combination intended for use with syringes for general purpose fluid injection/ aspiration and filtering. •The FROG removable filter allows the device to first withdraw medications from glass ampules and filter out glass fragments prior to subsequent administration after the removal of the filter cover. •The FROG device is intended to be used by health care practitioners supporting medical care of any patient where delivery of drug housed in a glass primary container (where there is potential for glass particulate to get into drug upon opening of said primary container) is required.	The needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.	Different The indications for use and intended use of the subject device and predicate device are similar. The FROG device has the additional technology of a filter. Design verification and validation testing of the filter demonstrate the difference does not raise new questions of safety and effectiveness. The intended use of the FROG is a needle for general purpose fluid injection/aspiration and filtering. The filter function on the subject device does not alter the indications for use for the hypodermic needle device.

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Intended Users	Licensed healthcare practitioners (Rx only)	Licensed healthcare practitioners (Rx only)	Equivalent. The subject and predicate devices are sold by prescription only and intended to be used by medical practitioners.
Principles of Operation	The FROG device incorporates a removable filter, which surrounds the hypodermic needle and allows the filtered aspiration of glass-contaminated drug into the syringe. After aspiration, the filter is removed from the device, permitting injection with the hypodermic needle which is already attached to the syringe.	The needles are attached to a syringe for use with injection and aspiration. It incorporates a sharpened bevel to permit access to medication containers and direct injection into patients.	Different The FROG device is a hypodermic needle (see predicate device) which incorporates a removable filter element (see reference device section below). Testing confirmed that the FROG is able to filter 5-micron particle as well as the reference device.

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Materials, Needle Guage and Dimensions	Body, 5ml Design: PP Boremed HD810MO Medical Grade, Gamma Stable Polypropylene, Natural molded by Medacys Seal: Precision Polymer Products Chlorobutyl 50D CP0-792, Natural Coated with Dow 360 Oil, 350 cSt Frog Filter: Porex BPE 0.45g/cc BD 18G 1.5in Needle: BD Mixed Materials – Polypropylene Stainless Steel Silicone	BD 18G 1.5in Needle: BD Mixed Materials – Polypropylene Stainless Steel Silicone	Different. The FROG device incorporates the predicate device as a component. The needle gauge and length are the same. Although there are new materials associated with the filtering function, the subject device was evaluated for safety in accordance with ISO10993-1. Differences in material raise no new types of safety or effectiveness questions with the subject device when compared to the predicate device.

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Technology and Design	The FROG device incorporates a removable filter, which surrounds the 18G, 1.5in hypodermic needle and allows the filtered aspiration of glass-contaminated drug into the syringe. After aspiration, the filter is removed from the device, permitting injection with the hypodermic needle which is already attached to the syringe.	BD conventional needles are known as BD PrecisionGlide™ needles. BD PrecisionGlide™ needle technology incorporates a thin wall, tri-bevel tip and BD micro bonded lubricant which is designed to provide ease of penetration. BD recently streamlined 16G-25G needles to a thin-wall configuration.* *27G, 30G and 18G blunt filter needles will remain regular wall	Different The FROG device incorporates the 18G, 1.5in needle of the predicate device and aspirates and injects fluids in the same manner. The filtration capability of the FROG device is similar to the reference device where both devices filter during the aspiration of liquid and are discarded prior to injection. Testing confirmed that the FROG is able to filter 5-micron particles using the reference device test method. These differences in technology and design raise no new types of safety or effectiveness questions with the subject device when compared to the predicate device.
Biocompatibility	Acceptable biological risk established by demonstrating that the device meets ISO 10993.	Acceptable biological risk established by demonstrating that the device meets ISO 10993	Equivalent.

Device Attribute	SUBJECT: [CarrTech] FROG (Filter Removal of Glass)	PREDICATE: [BD] BD Precision Glide Needle	Assessment of Equivalence
Sterilization	Sterile SAL 10^{-6} E-beam radiation	Sterile Gamma radiation	Different- All devices are sold as sterile. Sterility and performance testing after sterilization demonstrate the potential difference in sterilization does not raise new or different questions of safety and effectiveness.
Prescription	Rx only	Rx only	Subject and Predicate device – Equivalent

Reference Device:
The BBraun Filter Straw was used as a reference device. The BBraun Filter Straw features a polycarbonate hub, a sharp needle tip with a side bore for penetrating vials and filtering contaminants, and a 5-micron filter membrane tip. It is presumed to be used by licensed healthcare practitioners. The BBraun Filter Straw is attached to a syringe for aspiration of fluid from vials and ampoules by penetrating the media and providing a fluid path. It incorporates a filter for removal of particulates from the aspirating fluid. The filter is removed and discarded before using the aspirated fluid for injection.

Performance testing demonstrated that the filtration capability of the subject FROG device is equivalent to the reference device filtration specification (5 micron particles) where both devices filter during the aspiration of liquid and are discarded prior to injection. Testing also confirmed that when used to extract fluid from an ampoule with the filter shield in place, the residual volume remaining in the ampoule is comparable to the reference device.

The filtering feature of the subject device is not present on the predicate device but is present on the reference device which is used to filter liquid (drug) for the same purpose (same intended use). The intended use of the reference device is to filter the liquid prior to an injection or IV administration, which supports the indication of use for the subject device. Furthermore, CarrTech established performance requirements for testing the FROG device against the reference device at 5-microns. Thus, the new technological filter feature does not raise new questions of safety and efficacy versus the predicate device.

VIII. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

The following tests were performed to demonstrate that the proposed FROG device met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

a. Performance Testing

Performance Testing was conducted according to the following standards:

- ISO 7864: 2016 Sterile hypodermic needles for single use – Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- ISO 6009:2016 Hypodermic needles for single use – Color coding for identification
- ISO 594-1:1986 Conical fitting with 6% (Luer) taper for syringed, needles and certain other medical equipment – Part 1: General requirements
- ISO 594-2:1998 Conical fitting
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- FDA Guidance: Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”

Additional testing conducted:

- Filtration efficiency testing
- Residual volume testing
- Needle penetration testing

b. Biocompatibility

Biocompatibility testing was conducted in accordance with the FDA Guidance Document “Use of International Standard ISO-10993-1, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,” September 2023, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

The proposed FROG device is considered an externally communicating device for limited duration that indirectly contacts tissue.

Biocompatibility testing performed:

- Cytotoxicity Extraction Method (MEM Elution)
- Sensitization Guinea Pig Maximization Test (GPMT)
- Irritation Intracutaneous Irritation Test
- Acute Systemic Toxicity Testing
- Material Mediated Pyrogenicity Testing

Based on the results of the biocompatibility testing performed on the final FROG device, the subject device meets the requirements outlined in ISO 10993-1:2018.

c. Sterilization

The FROG device is provided sterile, sterilized with e-beam, and has a shelf-life of 6 months. The following testing was performed:

- Packaging and sterilization testing (ASTM D4169-22 (Simulated Shipping), ASTM F88/F88M-23 (Seal Strength Test), ASTM F1886/F1886M-16 (Visual Inspection), ATM F2096-11 (Bubble Leak Test))
- Shelf-Life testing through accelerated aging (ASTM F1980-21)
- USP 161 Bacterial Endotoxin testing
- ISO 11137-2 Third edition 2013-06 (including AMD1:2022, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]

d. Human Factors

Human Factors testing was conducted according to the following standards and guidance documents:

- ANSI/AAMI/ISO 14971 – Medical Devices – Application of risk management to medical devices.
- ANSI/AAMI/IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices, and its companion technical report 62366-2 Medical Devices – Part 2: Guidance on the application of usability engineering to medical devices.
- U.S. Food and Drug Administration (FDA). Application of Human Factors Engineering Principles for Combination Products: Questions and Answers. Guidance for Industry and FDA Staff.
- U.S. Food and Drug Administration (FDA). Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff.

IX. Conclusion

The proposed FROG device is substantially equivalent in intended use, mechanism of operation and fundamental technology, and similar materials compared to the predicate device, BD Precision Glide Needle (K021475). The intended use of the FROG is a needle for general purpose fluid injection/aspiration and filtering. The differences in the materials and the addition of the filter component between the subject and predicate device do not raise new questions of safety and effectiveness. The information provided in this submission demonstrates that the subject device is substantially equivalent to its predicate.