



December 22, 2025

EMED Technologies Corporation
Olena Whalen
QA/RA/CA Director
1262 Hawks Flight Court
Suite 200
El Dorado Hills, California 95762

Re: K251105

Trade/Device Name: Tetra (TM-20); Tetra (TM-50)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP, FRN
Dated: November 28, 2025
Received: November 28, 2025

Dear Olena Whalen:

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,


Jake K. Lindstrom -S

Jake Lindstrom, 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

Indications for Use

510(k) Number (if known)

K251105

Device Name

Tetra (TM-20);

Tetra (TM-50)

Indications for Use (Describe)

The EMED Tetra Micro Infusion System is intended for subcutaneous infusion for prescription liquid medicines for use in the home and hospital environment by adults and children (2 years and older), when administered according to the approved biologic or drug product labeling. The Tetra Micro Infusion System is indicated for use with:

- Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring.

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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510(k) Summary

K-number: 251105

Date Prepared: December 18, 2025

I. SUBMITTER (21 CFR 807.92(a)(1))

EMED Technologies Corporation
1262 Hawks Flight Ct., Suite 200
El Dorado Hills, CA 95762

Contact Person: Olena Whalen
Contact Person Title: QA/RA/CA Director
Tel: 916.932.0071 ext. 114
Email: owhalen@emedtc.com

II. DEVICE NAME (21 CFR 807.92(a)(2))

Device Trade Name: Tetra (TM-20); Tetra (TM-50)
Common Name: Infusion Pump
Classification Name: Immunoglobulin G (IgG) Infusion System
Regulation Number: 880.5725
Product Code: PKP, FRN

III. PREDICATE DEVICES (21 CFR 807.92(a)(3))

Primary: K240148, SCIg60 Infusion System (Product Code – PKP)
Secondary: K091042, Crono S-PID 50 (Product Code – FRN)

These predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION SUMMARY (21 CFR 807.92(a)(4))

The Tetra Micro Infuser is a reusable multi-patient use device, battery powered, prescription-only, designed to be used as a system for subcutaneous infusion using compatible syringes through EMED patient administration sets.

The syringe connects to the Tetra Micro Infuser, and the patient administration sets connects to the syringe. Patient administration sets are sterile and single use only.

There are 2 model options for the Tetra Micro Infuser: TM-20 (designed to connect to a 20mL syringe); and TM-50 (designed to connect a 50mL syringe). The TM-50 model can be used with 5 mL, 10 mL, and 20 mL syringe sizes when used with the optional Syringe Adapter (single-use, non-sterile; sold separately). Once attached to the syringe, the Syringe Adapter is not intended to be removed.

The patient administration sets are commercially available, previously marketed devices (K140131) and support the subject device without modification.



NOTE: Only the Tetra Micro Infuser, as the new system component, is within the scope of this 510(k). Patient administration sets and syringe models are not within the scope of this submission but are referenced when relevant. The Tetra Micro Infuser is to be used only with EMED patient administration sets.

The Tetra Micro Infuser is designed for use in home and healthcare facility environments.

The Tetra Micro Infuser functions by applying controlled pressure to the syringe stopper (gasket) to deliver medication through the connected patient administration sets.

The user interface consists of two buttons used to power the device on/off and to select discrete delivery settings. The resulting flow rate depends on the selected setting and system factors such as syringe size, medication viscosity, and downstream resistance.

The device provides visual and audible notifications for status and certain conditions. The device battery is charged through a USB-C port, and infusion is disabled during charging. There is no user-accessible wireless or networking connectivity, and USB communication is restricted to factory/service access.

The Tetra Micro Infuser does not require calibration. Periodic cleaning of external surfaces is recommended between uses, and the infuser should be disinfected by healthcare or facility personnel between each patient when transferring to a new user.

Each Tetra Micro model is packaged in a labeled box containing: one infuser (either Tetra Micro TM-20 or TM-50); one USB-C to USB-A charging cable; one Instructions for Use document; and one Quick Reference Guide document.

V. INTENDED USE/INDICATIONS FOR USE (21 CFR 807.92(a)(5))

Intended for subcutaneous infusion for prescription liquid medicines for use in the home and hospital environment by adults and children (2 years and older), when administered according to the approved biologic or drug product labeling.

The Tetra Micro Infusion System is indicated for subcutaneous infusion of:

- Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring)

Attribute / Feature	Tetra Micro (Subject Device)	SCIg60 Infusion System (K240148) (Primary Predicate)	CRONO S-PID 50 (K091042) (Secondary Predicate)	Equivalency
Intended Use	Subcutaneous infusion for prescription liquid medicines.	Subcutaneous infusion for prescription liquid medicines.	Subcutaneous infusion for prescription liquid medicines.	Equivalent
Indications for Use	<ul style="list-style-type: none"> • Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring) 	<ul style="list-style-type: none"> • Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring, 	Not cleared for a specific drug.	Equivalent

Attribute / Feature	Tetra Micro (Subject Device)	SCIg60 Infusion System (K240148) (Primary Predicate)	CRONO S-PID 50 (K091042) (Secondary Predicate)	Equivalency
		<ul style="list-style-type: none"> • Cuvitru Immune Globulin Infusion (Human) 20%, manufactured by Takeda, • Gammagard Liquid, Immune Globulin Infusion (Human) 10%, manufactured by Takeda, • Gamunex-C Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics, • Gammaked Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics, • Xembify Immune Globulin Subcutaneous (Human) 20%, manufactured by Grifols Therapeutics, and • Cutaquig Immune Globulin (Human), 16.5%, manufactured by Octapharma AG. 		
Prescription or Over the Counter	Prescription	Prescription	Prescription	Equivalent
Intended Population	Adults and pediatrics ≥ 2 years	Adults and pediatrics ≥ 2 years	Not specified	Equivalent
Use Environment	Home and hospital	Home and hospital	Home and hospital	Equivalent
Route of Administration	Subcutaneous	Subcutaneous	Subcutaneous	Equivalent

The EMED Tetra Micro Infusion System is intended for the subcutaneous administration of immunoglobulin therapies in home or healthcare settings. The device is indicated for use with Hizentra, a drug that is also cleared for subcutaneous administration with the identified predicate devices. The Tetra Micro Infusion System is used with EMED patient administration sets that are identical to those previously cleared for use with the primary predicate device. The use of the Tetra Micro Infusion System does not alter the intended use or performance of these administration sets. The device does not modify the intended use of the drug, the route of administration, or the patient population. Based on these factors, the indications for use of the Tetra Micro Infusion System are substantially equivalent to those of the predicate devices.

VI. TECHNOLOGICAL COMPARISON (21 CFR 807.92(a)(6))

Attribute / Feature	Tetra Micro (Subject Device)	SCIg60 Infusion System (K240148) (Primary Predicate)	CRONO S-PID 50 (K091042) (Secondary Predicate)	Equivalency
Principle of Operation	Pneumatic pump applies force to syringe gasket	Compression spring applies force to syringe plunger and gasket	Stepper motor-driven piston applies force to syringe gasket	Equivalent
Infusion Speed / Rate Selection	5 discrete pressure (speed) settings (Level 1-5)	Infuset or VersaRate flow control infusion sets	Screw-drive mechanism	Equivalent
Nominal Infuser Generated Pressure	2.50 -7.00 psig (level dependent)	1 bar (14.4 psig) average	Not published. Manufacturer only published flowrate specifications. Pressure is deduced as equivalent.	Equivalent
Maximum Operating Pressure	7.35 psig	1.16 bar (16.8 psig)	Not published. Manufacturer only published flowrate specifications. Pressure is deduced as equivalent.	Equivalent
Flow Rate Range	≤ 50 mL/h/site (expected rate per IFU tables; configuration-dependent)	≤ 50 mL/h/site (expected rate per IFU tables; configuration-dependent)	1 - 50 mL/h	Equivalent
Flow Rate Accuracy	EMED 26G Infusion Set: <ul style="list-style-type: none"> • 50mL up to ±19% • 20mL up to ±18% • 10mL up to ±27% • 5mL up to ±27% 	±14% to ±41% (based on flow controller and infusion set)	±3%	Equivalent
Flow Rate Vertical Sensitivity	± 30 cm (± 12 in) between Infuser and infusion site. When infuser is placed 30 cm (12 in.) above infusion site, up to 7% increase in flow rate. When infuser is placed 30 cm (12 in.) below infusion site, up to 7% decrease in flow rate.	Each 30.5 cm (12 in.) above infusion site: +6% from target flow rate Each 30.5 cm (12 in.) below infusion site: -4% from target flow rate	Not published	Equivalent
Occlusion Detection	Visual Inspection AND Pressure threshold-based with visual and audible notification.	None – visual inspection only.	Pressure threshold-based with alarm	Equivalent
End of Infusion Detection	Visual Inspection AND Pressure threshold-based with visual and audible notification.	None – visual inspection only.	Time to delivery shown on LCD	Equivalent
Compatible Syringes	TM-50: <ul style="list-style-type: none"> • 50 mL Hizentra PFS (NDC# 44206-455-25) • 20 mL Hizentra PFS (NDC#: 44206-458-96) using 20mL Adapter (FP-0010214) • 10 mL Hizentra PFS (NDC#: 44206-457-95) 	<ul style="list-style-type: none"> • 50 mL Hizentra PFS (NDC# 44206-455-25) • BD 50mL Syringe REF 309653 	Crono 50mL	Equivalent

Attribute / Feature	Tetra Micro (Subject Device)	SCIg60 Infusion System (K240148) (Primary Predicate)	CRONO S-PID 50 (K091042) (Secondary Predicate)	Equivalency
	using 10mL Adapter (FP-0010215) <ul style="list-style-type: none"> 5 mL Hizentra PFS (NDC#: 44206-456-94) using 5mL Adapter (FP-0010216) TM-20: <ul style="list-style-type: none"> 20 mL Hizentra PFS (NDC#: 44206-458-96) 			
Compatible Administration Sets	EMED OPTFlow Subcutaneous Administration Set	EMED OPTFlow Subcutaneous Administration Sets	Not Published	Equivalent
Architecture Type	Electro-mechanical	Mechanical	Electro-mechanical	Equivalent
Notifications	LED indicators and audible notifications	None – visual inspection only.	Acoustic + visual alarms	Equivalent
Software	Embedded firmware (microcontroller – controlled)	None	Embedded firmware (microcontroller – controlled)	Equivalent
User Interface	Membrane keypad with status LEDs and audible notifications	None	LCD, keypad, audible tones	Equivalent
Network Connectivity	None (USB-C for charging and restricted service/log access only)	None	None	Equivalent
Data Storage	Operational parameters only (e.g., usage counts and fault/notification history); no patient protected health information	None	Programmable values are automatically stored in the pump’s memory.	Equivalent
Sterility	Infuser: Non-sterile, reusable. Infusion set: sterile, single-use.	Infuser: Non-sterile, reusable. Infusion set: sterile, single-use.	Infuser: Non-sterile, reusable. Infusion set: sterile, single-use.	Equivalent
Power Source	Non-replaceable, Rechargeable, Lithium-ion, 3.7 VDC, 1000mAh	No battery - mechanical Spring	CR123A 3V lithium battery	Equivalent
Maintenance / Calibration	No calibration required, periodic external cleaning only	No calibration required, periodic external cleaning only	None	Equivalent
Operating Environment	<ul style="list-style-type: none"> Room temperature of 20 – 25 °C (68 – 77 °F), in order to limit temperature effect on fluid viscosity and flow rate. A 1 °C change in room temperature can change flow rate by 4.3%. Higher temperatures increase flow rate. 30 – 60% relative humidity, without condensation. Relative humidity does not 	<ul style="list-style-type: none"> Room temperature of 20 – 25 °C (68 – 77 °F), in order to limit temperature effect on fluid viscosity and flow rate. Humidity range – not specified Altitude range - not specified 	<ul style="list-style-type: none"> Operating Temperature Range: +10°C to +45°C Humidity range: 30 to 75% RH Altitude range: 700 – 1060 hPa 	Equivalent

Attribute / Feature	Tetra Micro (Subject Device)	SCIg60 Infusion System (K240148) (Primary Predicate)	CRONO S-PID 50 (K091042) (Secondary Predicate)	Equivalency
	have a significant impact to flow rate. <ul style="list-style-type: none"> 1.0 to 0.7 bar atmospheric pressure (sea level to 10,000 ft). Flow rate decreases approximately 1.2% for every 1,000 feet above sea level. 			
Storage Environment	<ul style="list-style-type: none"> Storage (between uses): Store the pump in a cool, dry place. Transportation temperature range (in original protective packaging): -30°C to +60°C Transportation humidity: <ul style="list-style-type: none"> At -30°C: RH uncontrolled At +40°C: 90% RH At +60°C: 15% RH 	Temperature: -5°C to +40°C Humidity – Not specified	Temperature: -10°C to +60°C Humidity: 10 – 100% RH	Equivalent
Infuser Size	64 x 64 x 41 mm 125 g	260 x 65 x 65 mm 412 g	84.5 x 55 x 42 mm 140 g	Equivalent
Useful Life	Up to 157 infusions	4,200 cycles	Two years against manufacturing defects	Equivalent

The Tetra Micro Infusion System achieves substantial equivalence through a combined comparison to two predicate devices.

The primary predicate, SCIg60 (K240148), is equivalent in the method of fluid delivery. Both systems apply pressure to a syringe to deliver immunoglobulin subcutaneously. In each case, the flow rate is not directly measured or adjusted based on flow feedback. Instead, flow is governed by the applied pressure/force, the viscosity of the fluid, and the resistance of the downstream subcutaneous administration set. For the Tetra Micro, pressure is regulated to the selected level via a closed-loop pressure control system; however, flow remains a resultant output and is not directly measured. The SCIg60 uses a spring to apply force to the syringe plunger rod, thereby displacing the stopper (gasket) and delivering the fluid. In contrast, the Tetra Micro uses a battery-powered pump under firmware control to generate pressure that is applied directly to the back of the stopper within the syringe barrel. In both cases, controlled pressure displaces the fluid through a passive administration set, and the actual flow rate is determined by system resistance and fluid properties.

The secondary predicate, Crono S-PID 50 (K091042), supports technological equivalence in energy source and control architecture. Like the Tetra Micro, Crono pump is a battery-operated, software-controlled infusion system. The Crono uses a stepper motor-driven piston to apply force to the syringe gasket, whereas the Tetra Micro applies pneumatic

pressure to apply force to the syringe gasket. Both devices employ embedded firmware and use microcontroller-based control to manage system functions. For Tetra Micro, a pressure sensor provides real-time feedback to maintain the selected pressure level (infusion speed) and expected infusion rates are provided in the IFU based on configuration; the system does not directly measure flow rate. The user selects one of five pressure levels (infusion speed) to match the prescribed delivery rate. The device provides LED indicators, audible notifications, and internal diagnostics. Infusion is disabled during charging. The device is not field-programmable and does not support wireless communication. The device does not require, request, retain, display, or store patient protected health information.

While the mechanical implementation of pressure differs, the subject and predicate devices share the same general approach in which flow is not directly measured/controlled using real-time flow feedback by the infuser. Other technological characteristics are comparable as summarized in the above table, including but not limited to syringe-based delivery, reusable non-sterile infuser used with sterile single-use administration components, and overall electro-mechanical architecture. These differences do not raise new questions of safety or effectiveness. Performance, lifecycle, electrical, software, cybersecurity, and usability testing support a determination of substantial equivalence.

VII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS (21 CFR 807.92(b))

No clinical study is included in this submission.

The following non-clinical tests were conducted:

- Infuser Operating Pressure
- Compatibility and Leakage
- Drug-Device compatibility
- Verification of Flow Rate Performance
- Verification of System Configurations against Drug Prescribing Information
- Cleaning and Disinfection Validation
- Useful Life Testing
- Drop Testing
- Electrical Safety and Electromagnetic Compatibility (Immunity and Emissions), including evaluation of audible levels and fluid exposure
- Home Use / Home Healthcare Environment Verification
- Software Verification and Validation (including cybersecurity evaluation as applicable)
- Shipping Validation
- Human Factors/Usability Validation (Summative Usability)
- Biological Evaluation
- Safety Assurance Case



The results of the non-clinical testing demonstrate that the subject device performs as intended and supports substantial equivalence to the SCIg60 Infusion System (K240148) and Crono S-PID 50 (K091042) with respect to safety and performance.