March 12, 2026

InVera Medical
Nigel Phelan
Unit 113, Innovation Hub,
Dublin Rd.,
Galway, H91 DCH9
Ireland

Re: K250794
Trade/Device Name: InVera Infusion Device
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: November 7, 2025
Received: November 7, 2025

Dear Nigel Phelan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.03.12 17:31:06 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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.

510(k) Number *(if known)*
K250794

Device Name
InVera Infusion Device

Indications for Use *(Describe)*
InVera Infusion Device is indicated for the infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature (e.g., superficial veins, saphenous veins).

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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510k Summary

510(k) #: K250794

Contact Details

Applicant Name	InVera Medical
Applicant Address	Unit 113, Innovation Hub, Dublin Rd., Galway H91 DCH9, Ireland
Applicant Contact Telephone	+353 91 455 960
Applicant Contact	Dr. Nigel Phelan
Applicant Contact Email	nigel@inveramedical.com

Device Name

Device Trade Name	InVera Infusion Device
Common Name	InVera Infusion Device
Classification Name	Cardiovascular
Regulation Number	870.1210
Product Code(s)	KRA

Legally Marketed Predicate Devices

510(k) #	**Predicate Trade Name**
K201907	ClariVein IC
	Reference Devices
K231148	Sclerosafe™
K210339	Bullfrog® Micro Infusion Device

Device Description Summary

The InVera Infusion Device is a minimally invasive, single-use, disposable catheter system designed for the controlled infusion of physician-specified agents into the superficial veins of the lower limb.

The InVera Infusion Device has been designed specifically for use in the peripheral vasculature, including the saphenous veins and related superficial veins of the lower limb, to ensure controlled navigation to the target site. It is typically introduced at the thigh, knee or ankle level via a 5Fr Introducer sheath.

The reinforced catheter design delivers pushability supporting direct access, without the requirement for a guidewire. The echogenic distal catheter section is visualized by ultrasound during navigation to the target site.

The nitinol helical coil is deployed from its constrained position in the distal catheter by a pin-and-pull handle mechanism. The helical coil can be recaptured and repositioned under direct ultrasound visualization to ensure proper placement in the target vein. The radial outward

force of the 6mm diameter coil and its micro-textured lumen engaging surface is intended to stimulate venospasm resulting in shrinkage of the target vein diameter., to cause dilution of the infused agent.

Prior to infusion of agents, the helical coil is withdrawn in the target vein by catheter shaft withdrawal by the user. This results in localized venospasm in the target infusion area and exposure of the subendothelial layer secondary to mechanical disruption by the lumen engaging surface of the helical coil. Infusion is performed by attachment of a syringe to the 3-way tap connected by an extension tube to the catheter handle luer hub. The infused agent is delivered through the catheter for end-hole infusion to the target zone. Infusion is typically performed at intervals across the target zone depending on the clinical requirement. Following completion of infusion, the helical coil is recaptured, and the device is removed.

Intended Use/Indications for Use

The InVera Infusion device is indicated for the infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature (e.g. superficial veins, saphenous veins).

Indications for Use Comparison

The InVera Infusion Device is substantially equivalent to the predicate ClariVein IC (K201907). The proposed indication for use of the InVera Infusion Device is the infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature (e.g. superficial veins, saphenous veins), this is identical to the predicate, ClariVein IC, K201907, with the exception of the inclusion of "sclerosant". There is no difference to the intended therapeutic use of the device as sclerosants are considered to be a subset of physician-specified agents.

Technological Comparison

The InVera Infusion Device and ClariVein IC have similar technological characteristics, overall design, principle of operation and design features, as described in the table below. The differences are detailed in the comparison table.

Comparison of Subject Device to Predicate Device:

Characteristic	InVera Infusion Device	ClariVein IC	Comparison
510(k) Number	K250794	K201907	N/A
Product Code	KRA	KRA	Equivalent
Regulation	870.1210	870.1210	The InVera Infusion Device is an infusion catheter that permits continuous intravascular flushing.

Characteristic	InVera Infusion Device	ClariVein IC	Comparison
Classification	II	II	Equivalent
Indications for Use	The InVera Infusion device is indicated for the infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature (e.g. superficial veins, saphenous veins).	The ClariVein IC is indicated for the infusion of physician-specified agents in the peripheral vasculature (e.g., superficial veins, saphenous veins).	Equivalent InVera Infusion Device has the same intended use as the predicate with the addition of specific language to reflect its compatibility with sclerosant, a commonly used type of physician-specified agent.
Components	The InVera Infusion device is comprised of a catheter assembly including shaft, infusion port and a nitinol coil with abrasive lumen engaging surface that is connected to a pin and pull handle mechanism for deployment and recapture of the coil following treatment.	The ClariVein IC is comprised of a catheter assembly, including the catheter shaft, infusion port, and rotatable wire, and is connected by means of a cartridge to an integral self-contained motor drive unit (MDU). The MDU includes the syringe support, handle grip, wire rotation speed selectors, and trigger features for physician-controlled infusion of a physician-specified agent.	Equivalent Both devices are low profile catheters with a fluid channel for delivery of physician-specified agents with end-hole infusion. Technological differences are that the InVera device utilizes a nitinol helical coil with lumen engaging abrasive surface to induce vasospasm and disrupt the inner lining of the vein to enhance infusion while the predicate uses a rotatable stainless-steel wire with angulated ball-tip connected to a motor for high-speed rotation to disperse infused agents. The InVera Infusion Device does not contain any motorized or electrically powered components.
Overall Design	Single-use catheter with nitinol helical coil and pin-pull handle mechanism with infusion port for delivery of physician specified agents.	Single-use catheter and motor drive unit. The catheter has a rotating wire tip for dispersing physician specified agents.	The InVera Infusion Device also consists of a sterile single-use low profile catheter for end-hole infusion.
Principle of operation	Mechanical abrasion of the vessel wall induces vasospasm and exposes media layer, thereby enhancing contact between the vessel and the infused sclerosant.	Minimally invasive endovascular approach using a motor driven spinning catheter used to disperse the infused agent onto the vessel wall.	Both the InVera Infusion Device and predicate provide end-hole infusion of physician-specified agents into the peripheral vasculature. Performance testing has demonstrated substantial equivalence.
Length	100 cm	45, 65 and 85 cm	InVera Infusion Device has a longer working length. No different questions compared to predicate.

Characteristic	InVera Infusion Device	ClariVein IC	Comparison
Diameter	5 Fr	3 Fr	5Fr is a commonly used size for venous interventions in this anatomy.
Infusion Aid	6 mm coil	Angled dispersion wire when in use has a diameter of circle in rotation of 12 mm.	Performance testing has evaluated the differences in design.
Lumen engaging surface	Micro-textured surface composed of contiguous triangular features.	Rotating ball tip on angulated wire at 3500 RPM.	Performance testing has evaluated the differences in design.

While there are technological differences between the two devices, both are infusion devices used for the delivery of agents into the peripheral vasculature. The technological differences between the InVera Infusion Device and the ClariVein IC have been evaluated through design verification and validation studies.

Non-Clinical and/or Clinical Test Summary & Conclusions

All the necessary performance testing has been performed for the InVera Infusion Device to assure substantial equivalence to its predicate and to demonstrate the subject device performs as intended. The performance of InVera Infusion Device was characterized through the following tests:

- Simulated use testing on the full device using an approach described in literature, FDA Guidance documents, and ISO 10555-1.
- Dimensional analysis on the device and its critical components using an approach described in literature, FDA Guidance documents, and ISO 10555-3.
- Deployment and Recapture analysis using an approach described in literature and FDA guidance documents.
- Catheter bond strength using a method based on the FDA Guidance document "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters".
- Flexibility and kink using a method based on the FDA Guidance document "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters".
- Inner Catheter torque analysis using an approach described in literature.
- Particulate evaluation using AAMI TIR42 Evaluation of particulate associated with vascular medical devices.
- Corrosion analysis using a test method based on ISO 10555-1.
- Infusion analysis using test methods based on ISO 10555-3, ISO 10555-1 and current literature.
- Catheter burst pressure and infusion flow rate using methods based on the FDA Guidance document "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters".
- Usability analysis on the device using a method based on IEC 62366-1 and FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices.

Pre-Clinical Ovine Study

The performance of the InVera Infusion Device was evaluated in a comparative, dual-arm, GLP study with the predicate device. The results demonstrate that the InVera Infusion Device performs in accordance with its intended use. Additional data from a clinical study was also used to interpret the results of the animal study. This was a prospective, single-arm clinical study where the InVera Infusion Device was used.

Substantial Equivalence Conclusion

The InVera Infusion Device has the same intended use, overall design, principle of operation, design features and similar technological characteristics as the predicate device. The technological differences between the two devices have been evaluated through the testing described within this submission and the results support the substantial equivalence. The InVera Infusion Device has been shown to be substantially equivalent to its predicate for its intended use.