April 29, 2025

Medex
% Haewon Park
Regulatory Affairs Associate II
Guerbet LLC
214 Carnegie Center, Suite 300
Princeton, New Jersey 08540

Re: K242255
Trade/Device Name: Qitexio® 4-Way Stopcock (QIT014)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FMG
Dated: March 26, 2025
Received: March 28, 2025

Dear Haewon Park:

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,

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.

510(k) Number *(if known)*
K242255

Device Name
Qitexio® 4-Way Stopcock (QIT014)

Indications for Use *(Describe)*
Qitexio® 4-Way Stopcock is intended to serve as a flow control and delivery device for I.V. fluids injection to the patient's vascular system. The device is indicated for medium pressure injection of fluids. It is also used for delivery of Lipiodol® (Ethiodized Oil) injection. It is intended for single use only. The device is not indicated for use in infusion.

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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K242255 - 510K Summary

I. OWNER

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II. Contact Person

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Date Prepared: April 29th, 2025

III. IDENTIFICATION OF THE SUBJECT DEVICE

Trade/Device Name:	Qitexio® 4-Way Stopcock (QIT014)
Common Name:	I.V. Set Stopcock
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class II
Product Code:	FMG

IV. PREDICATE DEVICE INFORMATION

Trade/Device Name:	Elcam High and Medium Pressure Stopcocks and Manifold (K123084)
Common Name:	I.V. Set Stopcock
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class II
Product Code:	FMG

V. DEVICE DESCRIPTION

Qitexio® 4-Way Stopcock is intended to serve as a flow control and delivery device for I.V. fluids injection to the patient's vascular system. Qitexio® 4-Way Stopcock is not intended to facilitate bi- directional flows, thus is not designed to be used in infusion. Qitexio® 4-Way Stopcock is designated for

single use only (disposable) and is MR safe. Qitexio® 4-Way Stopcock is robust under medium pressure and is verified to be used for Lipiodol (Ethiodized oil) delivery.

Qitexio® 4-Way Stopcock is made of a body with four ports (3 female and one male) and one handle with a L-Shape diverter. The L-shaped diverter opens two neighboring ports at the same time, creating a L-shaped communication channel. The male connector includes a mobile ring assembled on the end of male port, and it enables connection locking over female Luer. A small amount of lubricant is applied on the handle stem before placing it in the Stopcock body. The neighboring female port(s) is connected to the I.V. set to accept the delivered drug or fluid. One female port, that is on the opposite side of the male port, does not directly communicate with the patient (male port). This extra port is designed to enable users to inject multiple I.V. fluids, if needed.

The operating mechanism is manual and with a simple twisting handle position to determine direction of the fluids. Qitexio® 4-Way Stopcock has only two ports communicating at a time.

VI. INDICATIONS FOR USE

Qitexio® 4-Way Stopcock is intended to serve as a flow control and delivery device for I.V. fluids injection to the patient's vascular system. The device is indicated for medium pressure injection of fluids. It is also used for delivery of Lipiodol® (Ethiodized Oil) injection. It is intended for single use only. The device is not indicated for use in infusion.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Qitexio® 4-Way Stopcock, the subject device, is substantially equivalent to the legally marketed predicate, Elcam High and Medium Pressure Stopcock and Manifolds (K123084). Both are intended to serve as flow control and delivery devices for I.V. fluids injection to the patient's vascular system. Both devices are for single use only and are provided in the individually sterilized packages. Both devices have one male Luer that connects to patient with a mobile/rotating ring, which secures locking over female connection. Both devices can resist medium pressure up to 500 psi, making them ideal for the administration of I.V. fluids that require higher pressure.

Qitexio® 4-Way Stopcock is indicated to provide access ports for the delivery of Lipiodol, the iodinated contrast imaging agent. Medex has performed non-clinical bench performance and biocompatibility testing, to show that this technological difference does not raise any concerns for the safety or effectiveness of the subject device compared to the predicate.

Table 1. Substantial Equivalence Table for the Qitexio® 4-Way Stopcock and its predicate

Description	Qitexio® 4-Way Stopcock K242255 (subject device)	Elcam High and Medium Pressure Stopcocks and Manifold K123084 (predicate device)	Technological Features Differences
Indications for use	Qitexio® 4-Way Stopcock is intended to serve as a flow control and delivery device for I.V. fluids injection to the patient's vascular system. The device is indicated for medium pressure injection of fluids. It is also used for delivery of Lipiodol (Ethiodized Oil) injection. It is intended for single use only. The device is not indicated for use in infusion.	Elcam's High and Medium Pressure Stopcocks and High and Premium High-Pressure Manifolds are intended to serve as flow control and delivery devices for I.V fluids injection to the patient's vascular system. The devices are indicated for medium and high-pressure injection of fluids such as, but not limited to, fluids used during angiography and angioplasty and during interventional radiology and cardiology procedures. Devices indication for medium and high pressure does not preclude its use for low pressure procedures. The High and Medium Pressure Stopcocks and High and Premium High-Pressure Manifolds are intended for single use only.	Different Some technological differences such as Lipiodol compatibility of the stopcock have been tested and demonstrated that such differences do not raise new or different questions of safety or effectiveness.
Intended Patient Population	All adult and pediatric population who may need an administration of Lipiodol® and other solutions	All populations who may be subject to the device's intended use	Lipiodol compatibility of the stopcock has been evaluated under performance test.
Design - Number of side ports **Number of flow ways**	4 ports (3 female / 1 male) 4-Way	3 ports (2 female / 1 male) 4-Way	Difference in female port numbers was addressed under Use-Related Risk Analysis Study.

Single use?	Yes	Yes	No difference
Packaging	PET/PE pouch sealed with Tyvek lid	Tyvek or paper/polyethylene pouch	Different; The difference arises from adherence to two different industry practices and does not introduce any new or different questions of safety or effectiveness.
Transportation and Storage Condition	No special storage or transportation condition. Recommends to store in room temperature; store in dry and warm place, and not exposed to strong light.	NA	Industrial standards The sponsor assumes no significance difference
Principle of Operation	Manual twisting of handle Manually connect and/or disconnect with any compatible Luer fittings	Manual twisting of handle Manually connect and/or disconnect with any compatible Luer fittings	No difference

Overall shape	Body with 4 ports and a handle on the top	Body with 3 ports and a handle on the top	Different The overall shape of the subject device was evaluated for its dimensions, leakage, biocompatibility, and Luer connectivity under performance tests. This difference does not raise any new or different questions of safety or effectiveness.
Device Dimension	52.5mm(L) x 44mm(D) x 26.8mm(H)	NA	The sponsor assumes no significance difference
Maximum pressure	Up to 550 psi	MP stopcocks: Up to 500 psi HP stopcocks: Up to 1200 psi	Different The subject device has a maximum pressure rating of up to 550 psi, which falls within the range of medium- and high-pressure ratings of the predicate device. Therefore, this difference does not raise any new or different questions of safety or effectiveness.
Material	Polyamide (Body and rotator) Polybutylene terephthalate (Handle)	Polycarbonate LEXAN (Body, rotator) Acetal Ultraform (Handle)	Material differences are tested for biocompatibility, chemical characterization, torque, and burst tests.

Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference. Biocompatibility has been tested according to the same ISO standard.
Sterilization Method	Gamma Irradiation	EtO	Different; Industrial standards
Chemical resistance to Lipid	Yes (Lipiodol)	No	Lipiodol resistance of the subject device has been evaluated for 24 hours
Shelf life	3 years	Up to 1 year	Different The shelf life of the subject device has been verified by both accelerated and real-time aging. Therefore, this difference does not raise any new or different questions of safety or effectiveness.

As summarized in Table 1, Qitexio® 4-way Stopcock, the subject device, has the same intended use as the predicate device, with a restriction related to the fact that the subject device is not intended to high pressure injection of fluids.

The engineering design, physical shape, principle of operation, and the intended use of the subject device are substantially equivalent to the predicate device. Both devices are for the single use only, and both devices are provided in the individual sterilized packages. Both, the subject device and the predicate device, have one male Luer that connects to patient with a mobile/rotating ring that secures locking over female connection. Both subject device and the predicate device can resist medium pressure up to 500 psi, making them ideal for the administration of I.V. fluids that require higher pressure. In terms of chemical characteristics, such as Lipiodol resistance, shelf-life, and sterilization method, the sponsor has provided test reports that support the sponsor's claim that those differences do not raise any concern for using the subject device.

The subject device is different from the predicate in the following three main categories:

1) Difference in Physical Design
2) Difference in Chemical Composition of Materials
3) Difference in Lipiodol Resistance

The sponsor has addressed the differences in the above three categories as follows.

Physical Design:

Compared to the predicate, the subject device includes an extra female port and opens two ports at the same time using the L-shape diverter. The risks associated with the design differences, such as the additional female port and L-shaped diverter, have been addressed in URRA for US stopcock report. In the URRA report, the sponsor concluded that there was no use-related critical task due to the differences between the predicate device and the subject device. In addition, the overall shape of the Qitexio stopcock was evaluated for its dimensions, leakage, biocompatibility, and Luer connectivity. From URRA report, the sponsor concluded the differences between the subject device and the primary predicate device did not affect device safety and effectiveness.

Chemical Composition of Materials

The differences in the materials used for the stopcock construction have been evaluated through the biocompatibility studies per ISO 10993-1 series and through the chemical characterization study per ISO 10993-18 requirements. The housing body and mobile ring of the subject device are both made of polyamide, while the handle of Qitexio stopcock is made of polybutylene terephthalate.

In this chemical characterization study, the sponsor used hexane as the extraction solvent as representative of the clinical use of the device based on the non-polar physical properties of hexane being similar to nonpolar Lipiodol (Ethiodized Oil). Because hexane can extract organic additives better than Lipiodol, it was chosen as the worst-case extraction solvent.

Lipiodol Resistance:

Instead of evaluating the resistance of Qitexio® stopcock to lipids, such as triglycerides phospholipids and sterols, the sponsor evaluated 24 hours of physical resistance of Qitexio to Lipiodol to make the evaluation clinically more meaningful. Performance tests verified breakaway torque, mean torque during rotation, withstands pressure, and stop resistance torque of stopcock, demonstrating that the subject device maintains its physical performance characteristics after 24 hrs of exposure to Lipiodol®.

VIII. Performance Data

Sponsor used the FDA Guidance "*Intravascular Administration Sets Premarket Notification Submissions*," issued on July 11, 2008, to guide the list of performance data and standards. In this submission, the sponsor has identified the following regulatory standards and non-clinical performance tests for conformity.

Table 2. Performance Testing

Type of Tests	Recognized Consensus Standards	Conclusions
Bench Test		
Bore connectors with the Female & Male Luer Lock standard, Stopcock Body Pressure Withstand	ISO 80369-7 Second edition: 2021-05, Small bore connectors for liquids and gases in healthcare applications, part 7: Connectors for intravascular or hypodermic applications ISO 80369-20 First edition: 2015-05-15, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods	The test results are satisfactory for the requirements.
Mechanical and Chemical resistance to Lipiodol	Performance testing performed before and after 24h exposure to Lipiodol®.	Lipiodol® analysis report is compliant with the Medex internal criteria.
Stopcock Lever Rotation & Tightness	Verification of the stopcock requirement related to breakaway torque and mean torque during rotation.	Verification results met the Medex internal criteria.
Sterilization & Package Integrity		

Sterile Barrier Integrity Test	ISO 11607-1 Second edition:2019-02 (including AMD1:2023), Packaging for terminally sterilized medica devices – Part 1: Requirements for materials sterile barrier systems and packaging systems ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	The test results are satisfactory for the requirements.
Microbiological Validation of Sterilization Method	ISO 11137-1:2006, Sterilization of healthcare products – Radiation Part 1-Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11137-2:2013, Sterilization of healthcare products – Radiation Part 2 – Establishing the sterilization dose ISO 11737-1:2018, Sterilization of healthcare products – Microbiological methods Part 1- Determination of a population of microorganisms on products ISO 11737-2:2019, Sterilization of healthcare products – Microbiological methods Part 2 – Tests of sterility performed in the definition, validation and maintenance of a sterilization process	The test results are satisfactory for the requirements.
Biocompatibility		
Cytotoxicity	ISO 10993-5, 3rd edition 2009-06-01, Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity.	The test results are satisfactory for the requirements.
Irritation & Sensitization	ISO 10993-10, 4th edition 2021-11, Biological Evaluation of Medical Devices, Part 10: Tests for skin sensitization	
Acute Systemic Toxicity	ISO 10993-11, 3rd edition 2017 Biological Evaluation of Medical Devices, Part 11: Tests for systemic toxicity.	

Hemocompatibility	ISO 10993-4, 3rd edition 2017-04, Biological Evaluation of Medical Devices, Part 4: Selection of Tests for Interactions with Blood. ISO 10993-12, 5th edition 2021-01, Biological Evaluation of Medical Device, Part 12: Sample preparation and reference materials ASTM F756-17: Standard practice for assessment of hemolytic properties of materials	
Chemical Characterization - Extractables	ISO 10993-17, 2nd edition 2023, Biological Evaluation of Medical Devices, Part 17: Toxicological risk assessment of medical device constituents ISO 10993-18, 2nd edition 2020-01, Biological Evaluation of Medical Device, Part 18: Chemical Characterization of medical device material within a risk management process ISO/TS 10993-19, 2nd edition 2020, Biological Evaluation of Medical Device, Part 19: Physico-chemical, morphological and topological characterization of materials	
Material-mediated pyrogen	USP<151> Pyrogen Test	
Particulate Contamination Study	USP<788> Particulate Matter in Injection	The test results are satisfactory for the requirements.
Pyrogenicity		
Bacterial Endotoxins Test	USP <85> Bacterial Endotoxins Tests ANSI/AAMI ST72 (2011/R2016): bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing.	The test results are satisfactory for the requirements.
Transportation		
ISTA 3A Simulated Transportation Study	ISTA 3A-2018: Packaged-products for parcel delivery system shipment 70kg (150Lb) or less	The test results are satisfactory for the requirements.
User Related Risk Analysis		
Use Related Risk Analysis and Usability Engineering	FDA Guidance *"Human Factors and Usability Engineering to Medical Devices,"* Feb 2016	No Use-related critical task was identified due to differences between the predicate and the Qitexio®

	IEC 62366-1:2015, Medical Devices Part 1: Application of usability engineering to medical devices	4-Way Stopcock. No Human Factors Validation study was conduct.

IX. CONCLUSIONS

The Qitexio® 4-Way Stopcock is substantially equivalent to its predicate device. The intended use of the Qitexio® 4-Way Stopcock aligns with that of the predicate device, with the restriction that it is not intended for high-pressure injection of fluids.

Both devices are single use, individually sterilized, and feature a male Luer connection with a mobile/rotating ring for secure locking over a female connection. Both devices can withstand medium pressure up to 500 psi, allowing for administering IV fluids requiring higher pressure. Differences in Lipiodol resistance, shelf-life, and sterilization methods have been evaluated via non-clinical performance testing according to international standards and FDA guidance and demonstrated that these differences do not impact the device's safety or effectiveness, as confirmed by test reports.

The technological differences between the Qitexio® 4-Way Stopcock and the predicate device are minor and do not raise new questions of safety or effectiveness. The device's performance, as demonstrated through bench testing and biocompatibility studies (including chemical characterization), confirms that the Qitexio® 4-Way Stopcock performs as intended. The Qitexio® 4- Way Stopcock is substantially equivalent to the legally marketed predicate device, with no new concerns regarding safety or effectiveness.