March 14, 2022

Medex
% Matthew Helmi
Regulatory Affairs Associate
Guerbet LLC
821 Alexander Road, Suite 204
Princeton, New Jersey 08540

Re: K203738
Trade/Device Name: Qitexio Luer Lock Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 10, 2022
Received: February 11, 2022

Dear Matthew Helmi:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

CAPT Alan M. Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203738

Device Name
Qitexio Luer Lock Syringes

Indications for Use *(Describe)*
Qitexio Luer Lock Syringes are manual devices used to inject fluids into the body. They are also used for delivery of Lipiodol (Ethiodized Oil) Injection.

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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K203738 -510K Summary

Date: March 14th, 2022

Applicant/Sponsor
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Subject Device

Trade Name:	Qitexio® Luer Lock Syringe
Common Name:	Piston Syringe
Device Classification:	Class II
Regulation:	21 CFR 880.5860, Piston Syringe
Review Panel:	General Hospital
Product Code:	FMF (Syringe, Piston)

Predicate Device

Trade Name:	Merit Syringe
510(K) Number:	K173601

5.1. Device Description

Medex, a subsidiary of Guerbet Group, designed and manufactures the Qitexio® Luer Lock Syringe, a disposable, handheld syringe available in 3 different volumes (1, 3 and 20 mL). Qitexio® Syringes are standard syringes which are verified to endure the potentially damaging chemical effects of Lipiodol® (Ethiodized Oil), an oil-based contrast media manufactured by Guerbet.

Qitexio® Luer Lock Syringes are manual devices used to inject fluids into the body. Qitexio® Syringes are also used for delivery of Lipiodol® (Ethiodized Oil) Injection.
Lipiodol® (Ethiodized Oil) Injection is an oil-based radiopaque contrast agent indicated for:

- Hysterosalpingography in adults
- Lymphography in adult and pediatric patients
- Selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC).

They are single-use devices, sterilized by gamma radiation.

5.1.1 Subject Device Indication for Use (IFU) Statement

Characteristics	**Predicate Device** Merit Syringe (K173601)	**Subject Device** Qitexio® Luer Lock Syringe (K203738)
Indication for Use	The Merit Syringe is used to inject fluids into, and withdraw fluids from, the body.	Qitexio Luer Lock Syringes are manual devices used to inject fluids into the body. They are also used for delivery of Lipiodol® (Ethiodized Oil) Injection.
Prescription Only or Over the Counter	Prescription Only (Rx Only)	Prescription Only (Rx Only)

Table 1: Comparison of Indications for Use (IFU) Statements

Indication for Use (IFU) Statements – Discussion of Differences

The subject device (Qitexio® Luer Lock Syringe) and predicate device (Merit Syringe (K173601)) Indications for Use (IFU) statements differ in reflection of the narrower and more specific Indications for Use of the Qitexio® Syringe. The IFU are copied and compared in the table above, and differences further discussed below.

- Limitation to "injection of fluids into the body"
  - The Qitexio® Luer Lock Syringes subject device is indicated for injection of fluids into the body. The Merit Syringe predicate device is indicated for both injection of fluids into the body *and* withdrawing fluids from the body.

- Addition of a specific indication for Lipiodol® (Ethiodized Oil) Injection delivery.
  - In addition to general fluid injections, Qitexio® Luer Lock Syringes are indicated for delivery of Lipiodol® (Ethiodized Oil) by injection.

- Addition of this indication does not create a new or expanded indication compared to the Merit Syringe predicate device.

5.2. Substantial Equivalence

5.2.1. Comparison of Technological Characteristics with the Predicate device

The similarities and differences between the Qitexio® Luer Lock Syringes and Merit Syringe predicate are described in *Table 2* – Qitexio® *Luer Lock Syringes and Predicate Device Comparison* below.

Description	**Subject Device** Qitexio® Luer Lock Syringe (K203738)	**Predicate Device** Merit Syringe (K173601)	**Differences in Technological Characteristics**
Design	Standard five-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger, O-Ring, rotative finger flange, and backstop. Fitting offered with male luer lock. • Barrel • Finger flange • Backstop • Piston • Seal	Standard three-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip or O-Ring. Fitting offered with male luer lock. • Barrel (integrated finger flange and recess for backstop function) • Piston • Seal	***Different.*** ***See comment # 1*** (below table).
Material	The barrel is constructed from clear Polyamide; the plunger from polyamide material; the seal or O-Ring is made of silicone material.	The barrel is constructed from clear polycarbonate; the plunger from ABS material; the seal or O-Ring is made of silicone material.	***Different.*** ***See comment # 2*** (below table).
Principle of Operation	Manually operated by advancing and withdrawing the plunger within the barrel.	Manually operated by advancing and withdrawing the plunger within the barrel.	**Same as predicate.**
Operational Volumes	Operational volume of 1, 3 and 20 mL	Operational volume of 0.25, 1, 3, 6, 10, 20, 30 and 60 mL	***Different.*** ***See comment # 3*** (below table).

Description	**Subject Device** Qitexio® Luer Lock Syringe (K203738)	**Predicate Device** Merit Syringe (K173601)	**Differences in Technological Characteristics**
Graduation	Printed with accurate graduation lines that are compliant with ISO 7886- 1	Printed with accurate graduation lines that are compliant with ISO 7886- 1	**Same as predicate.**
Sterilization Method	Gamma radiation	Ethylene Oxide	***Different.*** ***See comment # 4*** (below table).

Table 2: Qitexio® Luer Lock Syringes and Predicate Device Comparison

Comment # 1 (Design) **–** The three (3) part design of the predicate device and five (5) part design of the subject device accomplish the same intended use. This and associated differences do not raise new questions of safety and effectiveness. Substantial equivalence to the predicate in safety and effectiveness with regard to design is supported by evidence of conformity to ISO 7888-1 and ISO 80369-7 further described in *Section 5.3.1. Performance Testing - Bench* below.

Comment # 2 (Material) **–** The differences in predicate and subject device syringe component/part materials described above do not raise new questions of safety and effectiveness. Substantial equivalence to the predicate in safety and effectiveness with regard to any difference in materials is supported through bench performance testing, Biocompatibility per ISO 10993 evaluation, and USP <788> particulate evaluation, further described in *Section 5.3.2. Biocompatibility Evaluation*.

Comment # 3 (Operational Volume) **–** The 1, 3, and 20 mL volumes in which the subject device is to be offered are also offered within the predicate device syringe range. This "difference" is thus limited to the subject device lacking several volume options offered by the predicate, which does not impact safety or effectiveness (as 1,3, and 20 mL are volumes offered by both the predicate and subject device).

Comment # 4 (Sterilization Method) **–** Both methods provide the same validated sterility assurance level of 10^{-6}. The difference does not raise new questions of safety and effectiveness. Substantial equivalence in safety and effectiveness with regard to sterilization method and related differences is supported by the evidence of sterilization validation per ISO 11137- 1:2006 – *"Sterilization of health care products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices."* as further described in *Section 5.3.3. Sterilization, Pyrogenicity, and Package Integrity Testing* below.

5.2.2 Substantial Equivalence Conclusion

The proposed Qitexio® Syringe incorporates an intended use encompassed by that of the predicate Merit Syringe, as well as similar materials, design, and principle of operation. Any differences in materials used, design, sterilization methods, and indications (delivery of Lipiodol® (Ethiodized Oil)

Injection) discussed in the comments above do not raise new questions of safety and effectiveness.

Conformity to Recognized Consensus Standards, Performance Testing requirements, and ISO 10993-1 Biocompatibility Evaluation as further described below establish the substantial equivalence of the proposed Qitexio® Syringe subject device to the Merit Syringe predicate device.

5.3. Data and Standards

An FDA Guidance and recognized consensus standards have been established for Piston Syringes under FDA Product Code FMF and 21 CFR 880.5860. A battery of tests was performed based on the requirements of the recognized consensus standards identified in below in *Section 5.3.1. Performance Testing Bench, Section 5.3.2. Biocompatibility Evaluation, and Section 5.3.3. Sterilization, Pyrogenicity, and Package Integrity Testing*. Conformity to these standards demonstrates that the proposed Qitexio Luer Lock Syringes met the established acceptance criteria for its Intended Use.

5.3.1. Performance Testing - Bench

The Qitexio Luer Lock Syringe subject device complies with FDA recognized consensus standards ISO 7886-1 *Sterile Hypodermic Syringes For Single Use - Part 1: Syringes For Manual Use* and ISO 80369-7 *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*, as outlined within this submission. Where applicable, performance specifications were defined and verified specifically for delivery of Lipiodol® (Ethiodized Oil) Injection. Functional performance testing of the subject device was performed using samples subjected to the various preconditioning schemes including double sterilization and accelerated and/or real-time aging.

5.3.2. Biocompatibility Evaluation

The testing performed on the proposed Qitexio Syringes subject device complies with ISO 10993 *Biological Evaluation of Medical Devices*. The subject device, including all of its patient (fluid) contacting materials (indirect – externally communicating), was found to be non-toxic and determined to be biocompatible for its intended use. The following Biocompatibility tests were performed based on patient contact type and duration criteria per ISO 10993.

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Hemolysis
- Material-Mediated Pyrogenicity (Rabbit)
- Chemical Characterization (Extractables Analysis) and Toxicological Evaluation

Particulate matter testing was conducted in accordance with USP <788> *Particulate Matter in Injections (Method 1 Light Obscuration Particle Count)* and met USP <788> 1B acceptance criteria (for ≤ 100 mL volume).

5.3.3. Sterilization, Pyrogenicity, and Package Integrity Testing

5.3.3.1. Sterilization

Each Qitexio Luer Lock Syringe is packaged as single unit in a sterile PETPE pouch sealed with a Tyvek lid (sterile barrier) and sterilized using Gamma Irradiation. Validation of the sterilization cycle was conducted in accordance with ISO 11137- 1:2006 – "Sterilization of health care products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.". VD max (Verification Dose maximum) is the specific method used for validation. The Qitexio Luer Lock Syringe requires 25 kGy of radiation based on this method as determined with ISO 11137-2:2013 – "Sterilization of health care Products – Radiation – Part 2: Establishing the Sterilization Dose". The Qitexio Luer Lock Syringe subject device will be sterilized with a dose comprised between 25 kGy and 50 kGy.

The SAL for the Qitexio Luer Lock Syringes is 10^{-6}.

5.3.3.2. Pyrogenicity

Material-mediated Pyrogens were evaluated through a Rabbit Pyrogen study according to USP 39 – NF 34 and European Pharmacopoeia (9th Edition) requirements. The results confirmed non-pyrogenicity.

Bacterial endotoxins were evaluated through the Limulus Amebocyte Lysate (LAL) test. The bacterial endotoxin rate measured by the LAL test, representative of a residual contamination of specific bacteria (gram), is to be verified once per year after the validation of the method, in the absence of critical changes in the process of manufacturing or packaging. As Qitexio Luer Lock Syringes have Indirect Contact with the Cardiovascular System, the endotoxin limit is < 20 endotoxin units, as determined by the LAL test criteria.

Thus, Qitexio Luer Lock Syringes are non-pyrogenic as indicated on the proposed labeling.

5.3.3.3. Package Integrity Testing

Each Qitexio Luer Lock Syringe is packaged as single unit in a sterile PETPE pouch sealed with a Tyvek lid (sterile barrier). Five (5) units are packaged in a secondary carton box, which comprises the sales unit box. Six (6) sales unit/secondary carton are then combined into a logistics unit/tertiary carton which contains a total of thirty (30) syringes for international shipment.

Package Integrity Testing performed after subject device samples exposed to ≥ 50 kGy (max dose) sterilization:

- Visual Inspection in accordance with ASTM F 1886/F 1886 M.
- Peel Characteristics (Width of the welding seam) according to ISO 11607-1.
- Peel Test (Sealing force) according to ISO 11607-1 and ASTM F 88/F 88 M.
- Dye Test according to ASTM F 1929.

Package Integrity Testing performed after subject device samples exposed to ≥ 50 kGy (max dose) sterilization and ISTA 3A Simulated Transportation methods:

- Visual Inspection in accordance with ASTM F 1886/F 1886 M.
- Peel Characteristics (Width of the welding seam) according to ISO 11607-1.
- Peel Test (Sealing force) according to ISO 11607-1 and ASTM F 88/F 88 M.
- Bubble test according to ASTM F 2096.

5.3.4. Shelf-Life

The Qitexio Luer Lock Syringe subject device has a labeled shelf-life of three (3) years from the date of manufacture if stored under normal conditions. The claimed three (3) year shelf-life is supported by acceptable results of device functionality testing and package integrity testing conducted on representative device samples subjected to three (3) years aging (real-time or accelerated aging equivalent), among other preconditioning methods (as summarized above under Sections *5.3.1. Performance Testing - Bench* and *5.3.3. Sterilization, Pyrogenicity, and Package Integrity Testing*).

5.4. Conclusion

The Qitexio Luer Lock Syringes have the same intended use as the predicate device. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness. Performance data (including Bench Testing) and evidence of Biocompatibility (including compatibility with Lipiodol® (Ethiodized Oil) Injection), have established that the Qitexio Luer Lock Syringes perform as intended. The subject device is thus substantially equivalent to the legally marketed predicate device.