December 18, 2024

Quest Medical, Inc.
Stephanie Edugie Ajayi
Regulatory Affairs Specialist
1 Allentown Parkway
Allen, Texas 75002

Re: K241058
Trade/Device Name: Lyka® PORT Needle Free Access Device (4170Y)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: November 18, 2024
Received: November 18, 2024

Dear Stephanie Edugie Ajayi:

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.

Submission Number *(if known)*

K241058

Device Name

Lyka® PORT Needle Free Access Device (4170Y)

Indications for Use *(Describe)*

Lyka® PORT needle free access device is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an I.V. Set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein or artery. The device may be used for patient populations including very low birth-weight infants, infants, children, and adults for up to 7 days.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K241058

510(k) Summary

Prepared on: 2024-12-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Quest Medical, Inc.
Applicant Address	1 Allentown Parkway Allen TX 75002 United States
Applicant Contact Telephone	9723326290
Applicant Contact	Mrs. Stephanie Edugie Ajayi
Applicant Contact Email	sajayi@questmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Lyka® PORT Needle Free Access Device (4170Y)
Common Name	Intravascular administration set
Classification Name	Set, Administration, Intravascular
Regulation Number	880.5440
Product Code(s)	FPA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K040710	Tego Needle Free Access Device	FPA

Device Description Summary

21 CFR 807.92(a)(4)

Lyka® PORT is a needle free accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an IV set. It consists of a housing made from Polycarbonate and a Stem made from Silicone Rubber. The materials used in Lyka® PORT meet the requirements of ISO 10993-1 and have a long history of acceptable use with blood, blood-related products and drug products. The device will permit access to a catheter without the use of needles. When used in a closed position, it has a flat, smooth surface. When the male connector of a syringe or secondary line is engaged into the device, the silicone stem opens in the middle creating a straight fluid path. When the male connector is removed from the device, its body forces the stem shut and maintains a sealed fluid path. A cap is not required to seal Lyka® PORT or to maintain sterility. The device will be sold as a sterile, single use device for use for up to seven (7) days.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Lyka® PORT needle free access device is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an I.V. Set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein or artery. The device may be used for patient populations including very low birth-weight infants, infants, children, and adults for up to 7 days.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Predicate Device - The TEGO Needle Free Access Device is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an Intravascular Administration Set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein or artery. The TEGO is a needle-free capping device which close the end of the catheter. The TEGO will permit access to the catheter without the use of needles and therefore passively aid
in the reduction of needlestick injuries.
Subject Device - Lyka® PORT needle free access device is intended for use as an accessory to a vascular access device (catheter) used in

Hemodialysis or as an accessory to an I.V. Set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein or artery. The device may be used for patient populations including very low birth-weight infants, infants, children, and adults for up to 7 days.
Both the predicate device (TEGO) and the subject device (Lyka® PORT) are intended for needle-free access to vascular devices for administering or withdrawing fluids. The fundamental indication is the same. The predicate includes statements about its capping mechanism and passive reduction of needlestick injuries. The subject device provides details about its intended patient populations in compliance with ISO 10993-7:2008 Amd 1:2019 (e.g., very low birth-weight infants, children, and adults) and duration of use (up to 7 days). The differences are descriptive and do not alter the intended use or clinical applications. The subject device is safe and effective for their intended purpose, as validated by biocompatibility, EO-ECH residual testing, and performance testing.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device, Lyka® PORT Needle-Free Access Device, demonstrates comparable technological characteristics to the predicate device, TEGO Needle-Free Access Device (K040710), as evaluated in accordance with the FDA's guidelines for substantial equivalence. Both devices share similarities in design, intended use, materials, and performance. Differences in flow rate, priming volume, maximum pressure tolerance, valve mechanism, and shelf life were analyzed and validated through performance testing, demonstrating that these differences do not affect safety or effectiveness.

Similarities:
Intended Use:
Both devices are needle-free accessories to vascular access devices for the administration or withdrawal of fluids. The intended use complies with 21 CFR 880.5440 and product code FPA.

Design and Functionality:
Both devices are needle-free, swabable, and luer-activated, designed to minimize dead space and ensure sterile access to vascular systems.

Performance:
Both devices meet critical performance requirements:

Flow rate:
Predicate Device: Straight fluid path accommodates flowrates >600 mL/min; Subject Device: Not greater than 600ml/min
Microbial ingress prevention: Effective barrier for seven days.
Surface disinfection: Achieved with 70% isopropyl alcohol in 30 seconds.

Materials:
Both devices use biocompatible materials for patient-contacting components:
Predicate Device: Polycarbonate, silicone rubber, and polyethylene (with trace silicone lubricant).
Subject Device: Polycarbonate Makrolon Rx-1805, Silicone Rubber Elastosil 3003/40, and Nusil 420/460 Silicone Lubricant.

Biocompatibility Testing:
The subject device meets ISO 10993-1 requirements, confirming safety for all patient-contacting materials. Testing results validate equivalence in material safety.

Sterilization and Packaging:
Both devices are sterilized with ethylene oxide (EO) and packaged in Tyvek pouches, ensuring sterility and stability during storage and transportation.

Clinical Use:
Both devices are approved for continuous use for up to seven days.

Differences and Justifications:

1. Flow rate:
Predicate Device: Straight fluid path accommodates flowrates >600 mL/min; Subject Device: Not greater than 600ml/min
The subject device's flow rate capacity is aligned with typical clinical requirements and is sufficient for its intended use. Testing confirms that the reduced flow rate does not impact safety or effectiveness.

2. Priming Volume:
a. Predicate Device: 0.06 mL; Subject Device: ~0.1 mL.
b. The subject device's slightly higher priming volume has been validated through performance testing, confirming it does not impact clinical safety or effectiveness.

3. Maximum Pressure:
   a. Predicate Device: >15 psi; Subject Device: 1550 mmHg (30 psi).
   b. The subject device's higher-pressure tolerance enhances robustness without compromising safety or effectiveness.

4. Shelf Life:
   a. Predicate Device: 5 years; Subject Device: 3 years.
   b. The subject device's 3-year shelf life is supported by real-time and accelerated aging studies, ensuring full functionality and safety over the designated period.

5. Valve Mechanism:
   a. Predicate Device: Includes an automatic positive displacement mechanism.
   b. Subject Device: Features a silicone valve mechanism with manual flushing guided by the IFU to prevent retrograde flow. Testing demonstrates equivalence in catheter patency and functionality.

6. Hemolysis and Biocompatibility:
   a. Predicate Device: Hemolysis and biocompatibility status unknown.
   b. Subject Device: Demonstrates compliance with ISO 10993-1 and ASTM F756, confirming it is non-hemolytic and biocompatible for its intended use. Mechanical hemolysis testing shows equivalence in blood damage levels.

7. Ethylene Oxide Residuals:
   Subject device complies with ISO 10993-7:2008, confirming residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) levels are within allowable limits for patient safety.

The above analysis determines that the subject device, Lyka® PORT Needle-Free Access Device, is substantially equivalent to the predicate device, TEGO Needle-Free Access Device (K040710), in terms of intended use, technological characteristics, and performance, in accordance with the FDA's guidelines for substantial equivalence evaluation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing includes Mechnical Hemolysis, Microbial Ingress, Flow Rate, Backpressure Leak, Leak testing under positive and negative pressure, Multiple/continuous activation (followed by leak testing under positive/negative pressure), Simulated use, endurance testing (followed by leak testing under positive/negative pressure), Pressure vs. Flow rate, and EO-ECH residuals testing per FDA recognized consensus standard ISO 10993-7:2008; ISO 10993-7:2008, AMD1: 2019 found on page 18 and 26.

No clinical testing was conducted on this device.

All bench testing was conducted on the Lyka® PORT to support a determination of substantial equivalence to the predicate device. Results of performance testing demonstrate that the device meets all established specifications necessary for consistent performance and that no new questions of safety or efficacy are raised.