January 26, 2024

LifeOutcomes LLC
℅ Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
P.O. Box 3018
Nederland, Colorado 80466

Re: K231282
Trade/Device Name: LifeOutcomes C-Quest™ Blood Culture Sampling Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: December 22, 2023
Received: December 26, 2023

Dear Thomas Kroenke:

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.

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,

Porsche Bennett

Porsche Bennett
For 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)*
K231282

Device Name
LifeOutcomes C-Quest™ Blood Culture Sampling Device

Indications for Use *(Describe)*
The LifeOutcomes C-Quest Blood Culture Sampling Device (C-Quest) is a device intended to collect a patient blood sample and sequester the first portion of the sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. It is used in conjunction with either a scalp vein set for venipuncture or access to an existing patient IV using an extension set. C-Quest may be used with a blood culture tube or a standard blood collection syringe.

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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K231282 - 510(k) Summary

Preparation Date:	26 January 2024
Submitter:	LifeOutcomes LLC 88 Inverness Circle East, Unit E-102 Englewood, CO 80112 USA
Submitter Correspondent	Mr. Robert J. McKinnon Phone: +1 (720) 797-8070 Email: jon@lifeoutcomes.us
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net +1 (303) 956 4232
Trade Name:	LifeOutcomes C-Quest™ Blood Culture Sampling Device
Common Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulation Name:	Blood Specimen Collection Device
Regulation Number:	21 CFR §862.1675
Product Code:	JKA
Predicate Device:	Steripath® Gen2 Blood Collection System (K192247)
Device Description:	The LifeOutcomes LLC (LO) C-Quest™ Blood Culture Sampling Device (C-Quest) is a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample. This reduces the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. C-Quest is intended for use by medical professionals. The C-Quest consists of three (3) major components: • the tee body assembly. • a universal culture tube holder, and • a third-party, FDA cleared, 5 ml diversion syringe.

K231282 - 510(k) Summary

Indications for Use: The LifeOutcomes C-Quest Blood Culture Sampling Device (C-Quest) is a device intended to collect a patient blood sample and sequester the first portion of the sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. It is used in conjunction with either a scalp vein set for venipuncture or access to an existing patient IV using an extension set. C-Quest may be used with a blood culture tube or a standard blood collection syringe.

Technology Comparison: The C-Quest employs the same or similar technological characteristics as the predicate device.

Characteristic	*Magnolia Medical Technologies, Inc. Steripath Gen2 Blood Collection System (Predicate Device - K192247)*	*LifeOutcomes LLC C-Quest Blood Culture Sampling Device (Subject Device - K231282)*	*Discussion of Differences*
Indications for Use	The Steripath® Gen2 Blood Collection System is a system to draw blood for in vitro diagnostic testing. The Steripath® Gen2 Blood Collection System is indicated for use as a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. Additionally, components of the system may be used for infusion following sample collection after disconnection of the Initial Specimen Diversion Device® (ISDD®). Venipuncture needles are indicated for short term infusion (less than 2 hours).	The LifeOutcomes C-Quest Blood Culture Sampling Device (C-Quest) is a device intended to collect a patient blood sample and sequester the first portion of the sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. It is used in conjunction with either a scalp vein set for venipuncture or access to an existing patient IV using an extension set. C-Quest may be used with a blood culture tube or a standard blood collection syringe.	Both C-Quest and the predicate are indicated for the collection of blood samples, and sequestration of the initial 1.5 ml of blood. C-Quest components are not indicated for infusion whereas the predicate device components are indicated for infusion after removal of the ISDD. The subject device is indicated for a subset of the predicate device's indication. The difference does not raise different questions of safety and effectiveness.
Product Code and Regulation	JKA, 21 CFR §862.1675. FPA, 21 CFR §880.5440.	JKA, 21 CFR §862.1675.	C-Quest components are not indicated for infusion whereas the predicate device components are indicated for infusion after removal of the ISDD. The subject device is indicated for a subset of the predicate device's indication. The difference does not raise different questions of safety and effectiveness.

K231282 - 510(k) Summary

Technology Comparison (continued):

Characteristic	*Magnolia Medical Technologies, Inc. Steripath Gen2 Blood Collection System (Predicate Device - K192247)*	*LifeOutcomes LLC C-Quest Blood Culture Sampling Device (Subject Device - K231282)*	*Discussion of Differences*
Initial Blood Volume Sequestered	1.5 to 2.0 ml.	A minimum of 1.5 ml, not to exceed 2.0 ml.	Same; a slight difference in how the sequestration amount is stated.
Single Use	Yes	Yes	Same.
Sterilization Method and Sterility Assurance Level	Ethylene Oxide (EO), SAL 10^{-6}.	EO, SAL 10^{-6}.	Same.
Labeled Non-pyrogenic	Yes.	Yes.	Same.
Shelf Life	1 year.	18 months.	C-Quest has an 18 month shelf-life supported by testing post-accelerated aging. Therefore, the difference does not raise different questions of safety and effectiveness.
Components	The Steripath Gen2 Blood Collection System includes: • Initial specimen diversion device (ISDD®). • Inlet accessory (venipuncture needle or extension set). • Outlet accessory (culture blood transfer adapter or blood collection syringes).	The C-Quest Blood Culture Sampling Device includes: • C-Quest diversion device. • Inlet accessory (venipuncture needle or extension set). • Outlet accessory (blood culture bottle or blood collection syringe).	Both the predicate and subject devices are systems that incorporate a blood diversion device, and inlet and outlet accessories. Both blood diversion devices initially sequester 1.5 to 2.0 ml of potentially contaminated blood and prevent backflow of the potentially contaminated blood into the uncontaminated blood sample. Both systems utilize inlet and outlet accessories, which allow venous access through either a venipuncture or extension line connected to a patient intravenous (IV) line. The C-Quest device was tested to demonstrate sequestration performance, backflow prevention, and syringe activation force. Therefore, the differences do not raise different questions of safety and effectiveness.

K231282 - 510(k) Summary

Technology Comparison (continued):

Characteristic	*Magnolia Medical Technologies, Inc. Steripath Gen2 Blood Collection System (Predicate Device - K192247)*	*LifeOutcomes LLC C-Quest Blood Culture Sampling Device (Subject Device - K231282)*	*Discussion of Differences*
Materials	Medical grade materials (stainless steel, PVC tubing, medical grade adhesives polycarbonate)	Medical grade materials (stainless steel, silicone, polypropylene)	Similar. The subject and predicate devices are comprised of medical grade materials; the difference in the specific component materials were tested to FDA recognized consensus standards to demonstrate biocompatibility compliance. Therefore, the difference does not raise different questions of safety and effectiveness.
Packaging	Chevron Pouch, 12" x 6" TPT-0270 to TPF-0524a	Chevron Pouch, 9" x 6" 60 gm/m^2 Arjo paper, glue coated heated sealed to 52µm PET/PE film.	While different materials, both pouches are comprised of materials routinely used for sterilized and sterilizable medical device pouches; the difference in the specific packaging materials were tested to FDA recognized consensus standards to demonstrate package integrity compliance. Therefore, the difference does not raise different questions of safety and effectiveness.
Mechanism of Action	User-controlled negative pressure to sequester 1.5 ml to 2 ml of the initial contaminated blood drawn into a chamber. A second, independent blood flow path, after the sequestration of this initial contaminated blood, is isolated from this chamber which prevents the contaminated blood from entering the non-contaminated blood sample.	User-controlled negative pressure to sequester a minimum of 1.5 ml of the initial contaminated blood drawn. Once the initial contaminated blood is drawn into the syringe, it is isolated in the syringe by the unidirectional check value in the C-Quest tee body assembly which prevents backflow of the initial contaminated blood from entering the non-contaminated blood sample. The subsequent blood flow is directed into a second, independent blood flow path, which could be either a blood culture bottle or into a blood collection syringe activated by the user pulling the plunger on the blood collection syringe.	Same.

K231282 - 510(k) Summary

Summary of Verification and Validation Activities:

Sterilization

The C-Quest sterilization process and sterilized product was validated in accordance with the following Standards and guidance document:

- *ANSI AAMI ST72: 2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.*
- *ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*
- *ISO 10993-7: 2008, Cor1: 2009, Am1: 2019, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.*
- *ISO 11135: 2014 – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.*
- *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, 21 Jan 16*

An analysis and use of adoption methods indicated that the C-Quest sterilization process and sterilized product complies with the applicable Standards and guidance document.

Summary of Verification and Validation Activities (continued):

Shelf-Life

The C-Quest sterile packaging has a shelf life of 18 months.

The C-Quest sterile packaging was tested for packaging integrity in accordance with the following Standards and guidance document:

- *ASTM F88-21, Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- *ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*
- *ISO 10993-7: 2008, Am1: 2019, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (including Amendment 1: Applicability of allowable limits for neonates and infants).*
- *ISO 11607-1: 2019 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- *ISTA 3A – 18, Packaged-Products for Parcel Delivery System Shipment 70kg or Less.*
- *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, 21 Jan 16*
- *Shelf Life of Medical Devices, Apr 91*

Test results indicated that the C-Quest sterile packaging complies with the applicable Standards and guidance document.

Summary of Verification and Validation Activities (continued):

Biocompatibility

C-Quest is considered a blood path indirect contact, external communicating device for limited contact (less than 24 hours).

The indirect patient-contact materials in C-Quest were tested for biocompatibility compliance in accordance with the following Standard and guidance document:

- *ISO 10993-1: 2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," 04 Sep 20.*

The following biocompatibility tests were performed:

- Cytotoxicity.
- Sensitization.
- Intracutaneous reactivity.
- Acute system toxicity.
- Material-mediated pyrogenicity.
- Hemolysis.
- Particulate testing per USP <788>.

Test results indicated that the C-Quest component materials comply with the applicable Standard and guidance document.

K231282 - 510(k) Summary

Performance Testing – Bench

C-Quest was tested for performance in accordance with internal requirements, and the following internal requirements, applicable Standards, and guidance document:

- *Sequestration Verification.*
- *Actuation Force Verification.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *ISO 8536-12: 2021, Infusion equipment for medical use – Part 12: Check valves for single use.*
- *ISO 14971: 2019, Medical devices – Application of risk management to medical devices.*
- *ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications.*
- *ISO 80639-20: 2015, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods.*

Test results indicated that C-Quest complies with internal requirements, applicable Standards, and the guidance document.

Clinical Testing

No clinical data was submitted in this submission.

Conclusion

The differences between the predicate and the subject device do not raise new or different questions of safety or effectiveness. The LifeOutcomes C-Quest™ Blood Culture Sampling Device is substantially equivalent to the Steripath® Gen2 Blood Collection System with respect to the indications and technological characteristics.