September 15, 2022

Elcam Medical ACAL
℅ Tali Hazan
Regulatory Affairs Consultant
Talmed Ltd.
Ramot-Naftali
M.P Upper Galilee, 1383000
Israel

Re: K211204
Trade/Device Name: SafePort™ Manifold (or Stopcock)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FMG
Dated: August 14, 2022
Received: August 16, 2022

Dear Tali Hazan:

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,

David Wolloscheck, Ph.D.
For Payal Patel
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)*
K211204

Device Name
SafePort(TM) Manifold (or Stopcock)

Indications for Use *(Describe)*
SafePort(TM) Manifold (or Stopcock) is a one or more multiple ports product, which is indicated to serve as a flow control and a conduit device for I.V fluids delivery to the patient's vascular system. The product is intended for delivering I.V drugs or fluids, allowing gravity feed, sampling, transfusion, bolus injection and elimination of reflux of fluids during operation.

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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K211204 510(k) Summary
Elcam Medical's SafePort™ Manifold (or Stopcock)

1. **Submitter Information**

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2. **Date of Preparation**

September 15, 2022

3. **Identification of Predicate Devices**

3.1. Primary Predicate Device: Closed Swabable Stopcock and Minimal Residual Volume Luer-activated Swabable-stopcock, cleared under K060231 on April 13, 2006.

3.2. Reference Device: SafePort Manifold™ (or Stopcock), cleared under 510(k) number K111016 on June 09, 2011.

4. **Identification of Subject Device**

Regulatory Information

Regulation Name: Intravascular administration set
Regulation Number: 880.5440
Product Code: FMG
Common Name: I.V. Set Stopcock
Proprietary/Trade name: SafePort™ Manifold (or Stopcock)

5. **Device Description**

Elcam modified SafePort™ Manifold (also identified as SafePort™ Manifold) is used in Operating Room (OR) and Intensive Care Unit (ICU) to assist the physician and mainly the anesthesiologist in delivering IV drugs and fluids during and after operation.
Elcam's SafePort™ Manifold is designated for single use only (disposable) and its recommended maximal use duration is up to 24 hours.
Liquid compatibility: Elcam's SafePort™ Manifold is compatible with common fluids used in I.V. therapy, anesthesia and monitoring, including blood transfusion. The SafePort™ Manifold is made of a body with 1-5 side ports and 1-5 handles (depends on the number of ports).

Each port has a male or female connector (luer). Male connectors also include a nut (rotator) for locking over the female luer of the connected component. A small amount of lubricant is applied on the handle stem before placing it in the Stopcock/Manifold body.

Operating mechanism is manual and simple operated by twisting the handle position to determine fluid direction.
Between each handle and port housing an Elastomer may be placed to function as a pressure Luer Activated Valve (LAV) as an option to standard open female luer. The LAV is welded to the manifold body's fluid line at the female side port(s) in order to avoid back flow (reflux) and to serve as closed port. A rotator is assembled on the proximal male port (which is connected toward the patient) in order to enable connection locking. The distal female port is connected to the I.V Set to accept the delivered drug or fluid. Open ports (female and male) may be provided with or without covers.

Design wise, the modified SafePort™ Manifold relies on Elcam legally marketed SafePort™ Manifold cleared under K111016 that was modified as follow:

The SafePort™ **Handle** was modified for better producibility: Elastomeric material was changed, a cone-shape was added to the handle stem at the sealing area, as well as "door" shape fluid entrance added instead of around the entire stem. Cosmetic/visual non-functional changes were also implemented. The SafePort™ **Body** was changed to fit the handle changes: The stopper, dimensions luer compliance with ISO 80369-7, side port LAV female thread connection improvements and cosmetic/visual changes. Additional green colorant was added to the existing **Caps**' colorants.

Transfusion use was added to the SafePort™ indications for use statement to align Elcam SafePort™ with all other Stopcock and Manifold products (as in the primary predicate device cleared under K060231) that share the same indications for use, basic fluid path design and material types. Labeling materials were revised to include the additional transfusion claim.

All modifications were evaluated using well-established tests' methods previously utilized by Elcam or conducted per FDA recognized consensus standards and provided as summary tabulated in a risk analysis format.

6. Indications for Use Statement

SafePort™ Manifold (or Stopcock) is a one or more multiple ports product, which is indicated to serve as a flow control and a conduit device for I.V fluids delivery to the patient's vascular system. The product is intended for delivering I.V drugs or fluids, allowing gravity feed, sampling, transfusion, bolus injection and elimination of reflux of fluids during operation.

7. Summary of Substantial Equivalence:

In all aspects the modified device discussed in this 510(k) Submission, substantial equivalency was established with the predicate device, as can be demonstrated in the table below:

Table 1: Substantial Equivalence (Comparison Table)

Feature	**Closed Swabable Stopcock and Minimal Residual Volume Luer-activated Swabable-stopcock (MRVLS)** **Primary Predicate Device (K060231)**	**SafePort™ Manifold (or Stopcock)** **Subject Device**	**Technological Features Differences**
Indication for use	Elcam Closed Swabable Stopcock and MRVLS is indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.	SafePort™ Manifold (or Stopcock) is a one or more multiple ports product, which is indicated to serve as a flow control and a conduit device for I.V fluids delivery to the patient's vascular system. The product is intended for delivering I.V drugs or fluids, allowing gravity feed, sampling, transfusion, bolus injection and elimination of reflux of fluids during operation.	Same indications for use. Some technological differences are discussed below.
Classification	Stopcock, I.V. Set, Product Code: FMG, Regulation Number: 880.5440, Panel: General Hospital.	Stopcock, I.V. Set, Product Code: FMG, Regulation Number: 880.5440, Panel: General Hospital.	No difference
Number of female side ports	One or multiple (according to the end user request).	One or multiple (according to the end user request).	No difference
Principle of Operation	Manual twisting of handle. with LAV on the side port(s).	Manual twisting of handle Two alternatives for operations: with female luer on the side ports or with LAV on the side ports.	Same LAV on the side port. Female ports were tested for leakage and luer tests per sec. 8.4, 8.5, 8.12 and 8.13 below.
Usage duration	Up to 24 hours	Up to 24 hours	No difference
Chemical Resistance (Lipid)	Up to 24 hours	Up to 24 hours	No difference
Maximum Pressure	Up to 2 bar (29 psi)	**With LAV:** Up to 2 bar (29 psi) **Standard Port:** Up to 3 bar (45 psi)	3 bar maximum pressure was tested for leakage test per sec. 8.4 below.

Feature	Closed Swabable Stopcock and Minimal Residual Volume Luer-activated Swabable-stopcock (MRVLS) **Primary Predicate Device (K060231)**	SafePort™ Manifold (or Stopcock) **Subject Device**	Technological Features Differences
Raw materials	**Fluid line and ports (body including rotator)** • Polysulfone • Polycarbonate	**Fluid line and ports (body including rotator)** Polysulfone Polycarbonate	No difference
	Handle Polyethylene	**Handle** Polyethylene with Elastomer	Handle elastomer tested for biocompatibility, torque and burst tests per sec. 8.1, 8.2-8.3, and 8.7 below).
	Handle's Elastomer is N/A for this product's handle.	**Handle's Elastomer** Green PE Thermoplast®.	
	Luer Activated valve (LAV) • **LAV's Cap:** Polycarbonate • **LAV's stem:** Lubricated blue Liquid silicone rubber	**Luer Activated valve (LAV)** • **LAV's Cap:** Polycarbonate • **LAV's stem:** Lubricated blue Liquid silicone rubber	No difference
	Lubricant Medical Silicone Fluid	**Lubricant** Medical Silicone Fluid	No difference
	Port Covers (Caps) Polypropylene	**Port cover (Caps)** Polypropylene	No difference
	Colorants • Light Blue • Green • Red • White • Yellow • Blue	**Colorants** • Light Blue • Green • Red • White • Yellow • Green (additional hue)	Green additional hued cap was evaluated for biocompatibility per sec. 8.1 below.
Material biocompatibility	Biocompatible according to ISO 10993-1 standard.	Biocompatible according to ISO 10993-1 standard.	No difference
Materials compatibility with sterilization agents	Gamma irradiation and EtO	Gamma irradiation and EtO	No difference

Feature	Closed Swabable Stopcock and Minimal Residual Volume Luer-activated Swabable-stopcock (MRVLS) Primary Predicate Device (K060231)	SafePort™ Manifold (or Stopcock) Subject Device	Technological Features Differences
Overall Shape	Body with side female closed port (LAV), distal female port and proximal male port; Assembled Handle (with or without MRVLS design)	Same as primary predicate device, except for certain dimensional and visual improvement which do not affect device overall shape and specification.	Differences were evaluated for dimensions, leakage biocompatibility and luer tests per sec. 8.1, 8.2-8.9, 8.12-8.13 and 8.15-8.17 below.
Shelf Life	5 years	3 years	Reduced shelf life, does not affect safety and effectiveness.
Device Sterilization method	Gamma irradiation	Gamma irradiation	No difference

Substantial Equivalence Discussion and Conclusion:

The above comparison table demonstrates that Elcam's modified SafePort™ Manifold (or Stopcock) is the same as the primary predicate device in all key features and therefore, it was concluded by Elcam that it is substantial equivalent to the predicate device. In terms of the design changes, it should be noted that all changes to the SafePort™ took place to fit production processes and marketing preferences. No changes took place to the subject device's basic specifications and testing methods. Acceptance criteria of all tests but one remained the same.
A difference of 1.5 PSI in the upper limit of the handle door burst pressure was concluded as non-sensible during clinical use and therefore does not affect the device safety and effectiveness and does not alter substantial equivalence criteria.
Like the primary predicate device, the subject device has the same indications for use, including the transfusion which was added to the modified SafePort™. Both devices rely on same or highly similar technology and are classified under same classification.

Certain differences between the subject device and the primary predicate device, do not affect the device safety and effectiveness and have been further supported by the above identified reference device. These differences are hereby discussed:

The handle elastomer exist in the modified SafePort™ does not exist in the primary predicate device. While the subject device contains side female port(s) with or without swabable port(s), the primary predicate device contains only swabable side port(s). The reference device was used to leverage test methods for these features.

The subject SafePort™ raw materials change (different elastomer grade and additional green colorant), and the design changes to the body, handle and LAV's cap, do not alter the basic shape of the device, did not raise new risks and were validated accordingly within the existing well-established specifications, test methods and acceptance criteria as discussed and presented in the 510(k) submission. Therefore, it was concluded that these changes do not affect the safety and effectiveness of the modified SafePort.

In terms of shelf life, so far, Elcam has validated the modified SafePort™ for three years which is less than the predicate device that was validated for 5 years. This difference narrows the claimed shelf life and therefore does not alter the safety and effectiveness of the modified device.

All other features as indicated in the comparison table, remains exactly the same as the predicate device.

In light of the above, it was concluded that the modified SafePort™ Manifold is substantially equivalent to its primary predicate device.

8. Non-Clinical Performance Testing

Performance tests were conducted successfully by Elcam in order to validate the changes presented in this 510(k) Submission using well established methods based either on recognized consensus standards or Elcam's internal existing test methods previously utilized for legally marketed devices. No deviations took place during the tests. The tests were as follows:

8.1. **Biocompatibility tests** were performed according to ISO 10993-1:2018 recognized consensus standard and additional parts for each test in conjunction with most current FDA's Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". All tests were performed on final-sterile devices. The biocompatibility tests that were conducted are:

- **8.1.1.** **Cytotoxicity** per ISO 10993-5:2009.
- **8.1.2.** **Maximization Sensitization** per ISO 10993-10:2010.
- **8.1.3.** **Intracutaneous Study** per ISO 10993-10:2010**.**
- **8.1.4.** **Acute Systemic Toxicity** per ISO 10993-11:2017.
- **8.1.5.** **Pyrogen Study – Material-Mediated** per ISO 10993-11:2017.
- **8.1.6.** **Hemolysis** per ISO 10993-4:2017.
- **8.1.7.** **Complement Activation** per ISO 10993-4:2017.
- **8.1.8.** **Partial Thromboplastin Time (PTT)** per ISO 10993-4:2017.
- **8.1.9.** **Platelet Activation** per ISO 10993-4:2017.

8.2. **Initial handle torque test** was conducted using method based on Elcam internal protocol as previously used for Elcam cleared I&S Manifold (K032393).

8.3. **Handle stopper torque (override) test** was conducted using method based on Elcam internal protocol as previously used for Elcam cleared SafePort™ Manifold (K111016).

8.4. **Leakage tests using pressure of 200 kPa (2 bar)** and **300 kPa (3 bar)** were conducted according to recognized consensus standard ISO 8536-10:2015.

8.5. **Leakage test using pressure of 50 kPa, (0.5 bar)** was conducted according to recognized consensus standard ISO 8536-10:2015.

8.6. **Vacuum test** was conducted according to recognized consensus standard ISO 8536-4:2010.

8.7. **Handle "door" burst pressure test** was conducted using method based on Elcam internal protocol as previously used for Elcam cleared SafePort™ Manifold (K111016).

8.8. **Chemical resistance test (Lipid resistance)** for 24 hours was conducted using method based on Elcam internal protocol as previously used for Elcam cleared SafePort™ Manifold (K111016).

8.9. **Flow rate test** was conducted according to recognized consensus standard ISO 8536-4:2010.

8.10. **Particulate contamination test** was conducted according to recognized consensus standard ISO 8536-4:2010.

8.11. **Subvisible Particulate Matter** test was conducted, according to USP <788>.

8.12. **Luer tests** were conducted according to recognized consensus standards ISO 80369-7:2016 and ISO 80369-20:2015 as follows:

- **8.12.1.** Positive pressure liquid leakage.
- **8.12.2.** Sub-atmospheric pressure air leakage.
- **8.12.3.** Stress cracking.
- **8.12.4.** Resistance to separation from axial load.
- **8.12.5.** Resistance to separation from unscrewing.
- **8.12.6.** Resistance to overriding.

8.13. **Luer dimensions measurement** was conducted using method based on Elcam internal protocol as previously used for Elcam cleared Stopcocks and Manifolds.

8.14. **LAV cap wiping effectiveness** was conducted according to AAMI TIR30:2011/(R)2016 standard, ISO 11737-1:2018 recognized consensus standard and with most current FDA's Guidance for Intravascular Administration Sets 510(k) submission.

8.15. **Flow rate test** was conducted according to recognized consensus standard ISO 1135-4:2015.

8.16. **Blood leakage test in low pressure** was conducted according to both ISO 1135-4:2015 and ISO 8536-10:2015 recognized consensus standards.

8.17. **Mechanical hemolysis (main line) of the SafePort™** was conducted according to recognized consensus standards ASTM F756-17 and ISO 10993-4.

8.18. **LAV Microbial Ingress Study** was conducted in accordance with AAMI/ISO CN27:2021 and FDA Guidance on Intravascular Administration Sets 510(k), dated July 11, 2008.

8.19. Shelf-life package tests were conducted after sterilization, shipping simulation and accelerated aging, as follows:

8.19.1. Sterilization, per ISO 11137-2 and ISO 11607-1.

8.19.2. Shipping simulation on worst case configuration, per ISO 11607-1 and ASTM D4169.

8.19.3. Accelerated aging, simulating the claimed shelf-life, per ASTM F1980-16.

8.19.4. Packaging integrity tests after shipping simulation and Gamma sterilization were successfully conducted as follows:

a) Bubble test, per ASTM F2096

b) Burst test, per ASTM F1140/F1140M

c) Peel test (manual) and a visual test after peeling, per ASTM F1886/F1886M.

d) Peel test (mechanical), per ASTM F88/F88M.

e) Dye test, per ASTM F1929.

f) Visual tests after pretreatments (shipping, accelerated aging and gamma sterilization), per Elcam internal procedure.

9. Clinical Test Conclusion

No clinical Study was performed for the purpose of this submission.

10. Substantially Equivalent (SE) Conclusion

After discussing substantial equivalency of the modified SafePort™ with its predicate device in terms of similarities and differences, intended use, and technological characteristics, it was concluded that none of the changes altered the device safety and effectiveness and that the criteria of substantial equivalence is met. The evaluation of the subject device performance tests also demonstrated that it is as safe and as effective as the legally marketed predicate devices and therefore substantial equivalent.