Elcam MEDICAL
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Special 510(k) summary for Elcam Medical Stopcocks and Manifolds with Safe2 Rotator

In accordance with 21 CFR 807.92 the following summary of information is provided

1. **Date prepared:**

   May 07, 2014

2. **Contact information for the 510(k) submission:**

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Elcam Medical's U.S. agent:	Mr. Amir Halperin President of Elcam Medical, Inc. 2 University Plaza, Suite 620, Hackensack, NJ 07601, USA T: (201) 457-1120 F: (201) 457-1125 Email: amir.halperin@elcam-medical.com

3. **Device name:**

   Proprietary/ Trade name: Elcam Stopcocks and Manifolds with Safe2 Rotator

   Common/ usual name: Stopcocks and manifolds with male luer lock rotator.

   Classification: Elcam Stopcocks and Manifolds with Safe2 Rotator have been classified as Class II devices under the following classification names:

Classification name	Product code	21 CFR ref.	Panel
Intravascular administration set	FMG	880.5440	General Hospital

4. **Predicate Device**

Elcam Stopcocks and Manifolds with Safe2 Rotator were found to be substantially equivalent to Elcam's stopcocks and manifold.
Elcam's stopcocks and manifolds are legally marketed devices which are cleared under 510(k) number K022895.

5. **Device Description**

Elcam Stopcocks and Manifolds with Safe2 Rotator are an additional variation in the Elcam's Stopcocks and Manifolds product-family.
The Safe2 Rotator component is male luer with a mounted and internally threaded rotator that is fixed on the stopcocks body with a modified male connector. Both components create a uniform straight fluid path.
The device uniqueness is that the Safe2 Rotator can freely rotate on the stopcock male connector axis preventing the formation of kinks and twists in the IV sets during or following manipulations. In addition, the rotation ability of the Safe2 Rotator provides health care providers with a convenient access to a stopcock side (vertical) port during injection and aspiration.

6. **Intended use**

Elcam Stopcocks and Manifolds with Safe2 Rotator are 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.

7. **Technological characteristics and substantial equivalence**

Elcam Stopcocks and manifolds with Safe2 Rotator are substantially equivalent to Elcam stopcocks and manifolds cleared under 510(k) number K022895.
This new stopcocks variation has the same indication for use, principle of operation, overall shape, sterilization method and shelf life as its predicate.
Without changing the way of use from the health care provider perspective, Safe2 Rotator component ensures a secured connection of the stopcocks with other tubing set components preventing inadvertent disconnection and allows performing easy injection/ aspiration through the male luer by twisting the rotator towards a health care provider.
There were no new questions regarding Elcam Stopcocks and Manifolds with Safe2 Rotator safety and effectiveness that were raised due to this modification.
Therefore, the modified and the original devices were judged as substantially equivalent.

8. **Performance data**

Testing related to functionality of Elcam Stopcocks and Manifold with Safe2 Rotator has been conducted in a series of non-clinical tests. It has demonstrated that the modified device is as safe and effective as its predicate.
Following is a list of the bench tests that were conducted following risk management process to evaluate the effect of the design modification:

- Compliance with the functional requirements of ISO 594-2 (lock fitting)
- Initial twisting force
- Secondary twisting force
- Liquid pressure resistance
- Disconnection force

9. **Conclusion**

The evaluation of our modified device performances demonstrated that it meets its specifications, labeling claims and that it is as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

Elcam Medical ACAL
Natasha Branzburg
Q.A. and R.A. Engineer
Kibbutz Bar-Am
MP Merom Hagalil
Israel 13860

Re: K141254
Trade/Device Name: Elcam Stopcocks and Manifolds with Safe2 Rotator
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FMG
Dated: July 6, 2014
Received: July 9, 2014

Dear Mrs. Branzburg:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

*If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141254

Device Name
Elcam Stopcocks and Manifolds with Safe2 Rotator

Indications for Use *(Describe)*
Elcam Stopcocks and Manifolds with Safe2 Rotator are 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman -S
Date: 2014.07.29 13:06:05 -04'00'

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