510(k) SUMMARY

JUN - 9 2011

[As Required by 21 CFR 807.92(c)]

Date Prepared: April 3, 2011

Applicant Name: Elcam Medical ACAL

Kibbutz BarAm, Merom Ha Galil 13860, Israel

Contact Person Name: Ms. Natasha Evronyan – R.A. and Q.A. Engineer

Telephone: 972-4-6988821

Fax: 972-4-6980777

E-mail: Natasha.ev@elcam.co.il

Elcam Medical's U.S. Agent: Mr. Lloyd Fishman – President

Elcam Medical, Inc.

2 University Plaza, Suite 620,

Hackensack, NJ 07601, USA

Phone: 201- 457- 1120

Fax: 201- 457- 1125

E-mail: Lloyd.fishman@elcam-medical.com

Predicate Device:

Elcam's *Induction & Sampling Manifold (or Stopcock)* cleared under 510(k) # K032393.

Device Name

Common/ Usual Name: *SafePort Manifold™ (or Stopcock)*

Proprietary/ Trade Name: *SafePort Manifold™ (or Stopcock)*

Classification: Elcam's SafePort Manifold has been classified as Class II device under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Intravascular Administration I.V. Set	FMG	880.5440	General Hospitals

Device Description:

Modified *SafePort Manifold (or Stopcock)* is a redesign of *Induction & Sampling Manifold (or Stopcock).* It has the same appearance and intended use while several design modifications were introduced in order to contribute to the device's convenience of use and robustness. The device will be available in two (2) versions – swabable or standard ports configurations. The first version, standard port configuration is similar to the predicate device but with more robust design. The second version, besides of the design changes have an additional feature. The feature is the swabable valves which can be incorporated into the female side ports and function as a closed luer activate valve. The swabable valve enables the female port (luer) to be closed when it is not in use and saves the need to close it with a cap in order to avoid leakage and/ or port's contamination and serves as a needleless injection site integrated in the stopcock. Devices having the swabable valves have been demonstrated in a 510(k) submission for Elcam's Closed Stopcock.

SafePort Manifold or Stopcock is composed of the following components:

- One piece injected body having a side female ports. (with or without swabable valves according to the end user request)
- Handles assembled into the female side ports.
- Elastomer placed between each handle and side female port body, which is placed to function as a pressure activated valve activated valve.
- Rotor assembled to the male port (connected toward the patient) for connection locking.
- Check valve assembled to the male port which is connected toward the patient in order to enable connection locking. (this part will not be included, unless otherwise requested by the end user)
- Port covers and colored buttons. (if requested by an end user)

Indication for Use:

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

Technological Characterizes and Substantial Equivalence:

Elcam's modified *SafePort Manifold (or Stopcock)*without luer activated/ swabable valves has the same indication for use, principle of operation, shape, sterilization method and shelf life as its main predicate Induction and Sampling Manifold (or Stopcock).

The modified *SafePort Manifold* with luer activated/ swabable valves, a new feature cleared in the 510 (k) submissions *for Closed Stopcock (MRVLS)* is also the same as the predicate from the aspects mentioned above except for principles of operation requiring the specific treatment for the valves. The same principles have been introduced in the 510(k) submission for *Closed Stopcocks (MRVLS).*

There were no questions regarding the new product safety and effectiveness that were raised due to the non- identical technological characteristics.

Performance Data:

Testing relating functionality of the *SafePort Manifold*'s different variation has been conducted in a series of non-clinical tests presented in Section 7 of the submission. It was shown that the modified device is as safe and as effective as its predicates.

Clinical Data:

No clinical trials have been preformed for the modified *SafePort Manifold.*

Conclusion:

It was demonstrated that the modified *SafePort Manifold* is substantially equivalent to its predicate, *Induction & Sampling Manifold (or Stopcock),* and do not raise any questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Natasha Evronyan
O.A and R.A. Engineer
Elcam Medical A.C.A.L.
Kibbutz Bar-Am
MP Merom HaGalil, Israel 13860

JUN - 9 2011

Re: K111016
Trade/Device Name: Safeport Manifold™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 24, 2011
Received: May 31, 2011

Dear Ms. Evronyan:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Elcam Medical

Indication for Use Statement

510(k) Number (if known): _____

Device Name: Safeport Manifold

Indications for Use: *Safeport Manifold* 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 1.V drugs or fluids, allowing gravity feed, sampling, bolus injection and elimination of reflux of fluids during operation

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Acting for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111016