K060231

Elcam Medical

APR 13 2006

SPECIAL 510(K) SUMMARY FOR ELCAM'S CLOSED SWABABLE STOPCOCK (OR MRVLS)

DATE PREPARED: APRIL 7, 2006

1. 510(K) OWNER NAME

Elcam Medical ACAL
Kibbutz BarAm, Merom HaGalil 13860, Israel

Submitter person name: Ms. Tali Hazan – R.A Specialist
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ELCAM MEDICAL'S U.S AGENT:
Elcam Medical, Inc.
2 University Plaza, Suite 620, Hackensack, NJ 07601, USA

Contact Person: Mr. Ehud Raivitz – CEO
Telephone: 201-457-1120, *Fax:* 201-457-1125,
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2. DEVICE NAME

Common/Usual Name: *Closed Swabable Stopcock* and **MRVLS*
Proprietary/Trade name: *Closed Swabable Stopcock* and **MRVLS*
MRVLS = **Minimal **R**esidual **V**olume **L**uer-activated **S**wabable-stopcock

Classification: Elcam's *Closed Swabable Stopcock* (or *MRVLS*) has been classified as **Class II** devices under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Stopcock, I.V. Set	FMG	880.5440	General Hospital

3. PREDICATE DEVICES

Elcam's *Closed Swabable Stopcock* (or *MRVLS*) is substantially equivalent to Elcam's Stopcocks and Manifolds cleared under 510(k) number **K022895.**

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4. DEVICE DESCRIPTION

Modified Device and change Description: Elcam Medical's ***Closed Swabable Stopcock* and *MRVLS*** is a similar version of Elcam legally marketed stopcock, cleared under 510(k) number K022895.

The ***Closed Swabable Stopcock*** includes an addition of a component that functions as a closed luer-activated valve.

The **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. Once a male luer is introduced into the **closed** port the fluid path automatically opens to allow injection or blood sampling. Once the male luer is taken out, the female port is automatically closed.

The valve actually serves as a needleless injection site integrated in the stopcock. The only change from the end user point of view is the need to swab the valve's top (injection site) with aseptic fluid such as alcohol prior to male luer insertion.

The ***MRVLS (Minimal Residual Volume Luer-activated Swabable-stopcock)*** feature, is an additional option that can be added to the ***Closed Swabable Stopcock***, described above, and provides a stopcock with a **minimal residual volume**.
Conventional stopcocks are made of a body and a handle with a fluid path bore that allows the fluid to flow only through the handle. Therefore, it leaves other areas in the stopcock without a continuous flow through the stopcock fluid path and especially through the side port female luer. The *MRVLS* feature enables fluid flow **around** the handle so the fluid constant flow accesses the entire stopcock's internal volume and enables a continuous flow through the stopcock fluid path and through the side female luer during the medical procedure. This feature significantly reduces the "residual volume" in the stopcock and helps to keep the cleanliness of the stopcock's fluid path when it is in use.
The feature of *minimal residual volume* is achieved thanks to a modification in the stopcock handle design, which changes the fluid path and a flow guide formed therein.
The *minimal residual volume* design, together with the *luer-activated valve* creates the **M**inimal **R**esidual **V**olume **L**uer-activated **S**wabable-stopcock (***MRVLS***).

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The ***colorant and raw materials*** changed and/or added are all validated to their intended use and evaluated for biocompatibility.

All body/fluid contact materials that compose the modified device: *Closed Swabable Stopcock* and *MRVLS* were tested for biocompatibility in accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2003 - Biological evaluation of medical devices – Part 1: Evaluation and testing* with acceptable results.

5. INTENDED USE

Elcam *Closed Swabable Stopcock* (or *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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Elcam's Closed Swabable Stopcock (or MRVLS) is substantially equivalent to Elcam's conventional legally marketed Stopcock cleared by 510(k) number K022895. Elcam's new product and the predicate devices have the same indication for use, same basic shape, characteristics, materials, manufacturing technology and design.
The modified device differs from the predicate device in some characteristics such as the addition of the valve assembly and the design change in the MRVLS handle. These differences are not affecting the device's intended use or alter the device's fundamental scientific technology. The device is, therefore, as safe and as effective as the predicate device.

7. NONE CLINICAL PERFORMANCE DATA

Tests results are supporting all labeling claims and substantial equivalency. The modified device was tested with accordance to Elcam's legally marketed device specification and all acceptance criteria were met.

Biocompatibility and chemical tests, material characterization and risk assessment were performed on the patient-contact and fluid path materials of Elcam's modified device with satisfactory results.

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8. CONCLUSIONS

The evaluation of Elcam's *Closed Swabable Stopcock* (or *MRVLS*) non-clinical tests demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device. Therefore, we believe it is substantially equivalent to the Elcam's legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

Ms. Tali Hazan
Elcam Medical A.C.A.L.
Kibbutz BarAm
D.N. Merom Hagalil, 13860
Israel

Re: K060231
Trade/Device Name: Closed Swabable Stopcock and Minimal Residual Volume Luer – activated Swabable-stopcock
Regulation Number: 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FMG
Dated: March 13, 2006
Received: March 16, 2006

Dear Ms. 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 (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.

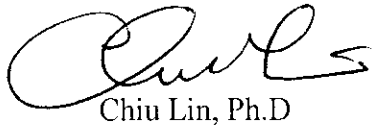
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Indications for Use

510(k) Number (if known): K060231

Device Name: Closed Swabable Stopcock and *MRVLS)

**MRVLS – Minimal Residual Volume Luer-activated Swabable-Stopcock*

Indications 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.

Prescription Use ✓ (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)

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(Posted November 13, 2003)

Anthony D. Watson

...ogy, General Hospital,
...ol, Dental Devices

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