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MAY 11 2006

510(K) SUMMARY FOR ELCAM ANTIMICROBIAL STOPCOCK [OR MANIFOLD]

DATE PREPARED: APRIL 3, 2006

1. 510(K) OWNER NAME

Elcam Medical ACAL
Kibbutz BarAm, Merom HaGalil 13860, Israel

Submitter & Contact person name: Ms. Tali Hazan – R.A Specialist
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2. DEVICE NAME

Common/Usual Name: Antimicrobial Stopcock [*or* Manifold]
Proprietary/Trade name: Elcam B-Stop
Classification: Elcam Antimicrobial Stopcock 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 *Antimicrobial Stopcock [or Manifold]* is substantially equivalent to Elcam's Stopcocks and Manifolds cleared under 510(k) number **K022895.**

For the antimicrobial feature, it is substantially equivalent to Medex's MX531-1LT Antimicrobial IV Set Stopcock and MX491T Antimicrobial Luer Lock Plug cleared under 510(k) number **K954970.**

4. DEVICE DESCRIPTION

Elcam *Antimicrobial Stopcock* [or *Manifold*] is identical to Elcam conventional legally marketed Stopcocks. A model of typical Stopcock is illustrated in Figure 1, section 11, page 33 of this submission.

Stopcocks and Manifolds have port(s) that provide access for medications injection, IV administration and blood sampling. The *Stopcock* usually has three ports and a handle that directs the fluid flow. It has **one** female side port that is used for medication injection or blood sampling. Both opposite ports (female/male) are connected to the IV line. The *Manifold* is assembled from two to five stopcocks bonded to each other to create a "stopcocks line" so the Manifold can have between two to five side ports for injection or sampling. Naturally, when the port is open, it can be a potential portal of entry for microorganisms into the device fluid path.
Elcam's *Antimicrobial Stopcock* [or *Manifolds*] provides an effective solution in preventing/reducing bacterial colonization in the device.

The antimicrobial agent is based on silver like in Medex's antimicrobial stopcock legally marketed device, cleared by 510(k) number K954970.

All body/fluid contact materials that composed the *Antimicrobial Stopcock* were tested widely for chemical and 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 *Antimicrobial Stopcock* [or *Manifold*] 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.

Elcam *Antimicrobial Stopcock* [or *Manifold*] has a feature of an antimicrobial agent using a compound containing silver.
The inclusion of an antimicrobial agent into the material formulation is intended to prevent/reduce the growth of contaminants on the device.

The device is NOT intended to be used as a treatment for patient infections.

5.1 The indications for *Antimicrobial Stopcock* [or *Manifold*] and its predicate devices are the same except for the following:

5.1.1 Elcam's legally marketed *Stopcocks* indication for use does not include the antimicrobial feature as no antimicrobial agent exists in these devices.

5.1.2 Medex's *Antimicrobial IV set Stopcock and Antimicrobial luer lock plug* indication for use has additional reference to the luer lock plug component. Elcam does not refer to the plug separately but as possible device variation.
- Elcam plugs do not include the antimicrobial agent and continue to function traditionally.

These two exceptions are not critical to the intended therapeutic use of the device and do not affect the safety and effectiveness of the device.

Note: Due to the similarity between Elcam's Stopcocks and Manifolds, henceforth the word Stopcock is referring also to Manifolds and may be used interchangeably unless specifically mentioned otherwise.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Elcam's Antimicrobial Stopcock is substantially equivalent to Elcam's conventional legally marketed Stopcock cleared by 510(k) number K022895 and to Medex's legally marketed Antimicrobial Stopcock cleared by 510(k) number K954970. Elcam conventional stopcock does not have the antimicrobial feature. Medex's Antimicrobial Stopcock completes the new device substantial equivalency. Elcam's new product and the predicate devices have the same indication for use, same basic shape, design, characteristics, materials, manufacturing technology and same antimicrobial agent (silver ions) mechanism. Elcam's *Antimicrobial Stopcock* combines the two predicate devices into one device that has an added value to the product therapeutic use and helping to protect the patient from device-related infections.

In both, the antimicrobial new device and Medex predicate device, the antimicrobial agent is incorporated into the stopcock raw material and the devices were tested widely for their intended use.

7. NONE CLINICAL PERFORMANCE DATA

Standard testing related to functionality (mechanically and microbiologically) of the new device has been conducted on Elcam *Antimicrobial Stopcock*. Extensive tests were performed with a variety of organisms in order to establish the new device effectiveness by demonstrating significant reduction of bacteria levels (at least 2 log). Mechanical tests were performed according to Elcam conventional stopcock specification with acceptable results.

Tests results are supporting all labeling claims and substantial equivalency. Biocompatibility and chemical tests, material characterization and risk assessment were performed on the patient-contact and fluid path materials of Elcam's *Antimicrobial Stopcock* with satisfactory results.

8. CONCLUSIONS

The evaluation of Elcam *Antimicrobial Stopcock* non-clinical tests demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2006

Ms. Tali Hazan
Regulatory Affairs Specialist
Elcam Medical, A.C.A.L.
Kibbutz BarAm
Merom HaGalil 13860
ISRAEL

Re: K053405
Trade/Device Name: Antimicrobial Stopcock [or Manifold], B-Stop
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: March 9, 2006
Received: March 14, 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 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 begin 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), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Indications for Use

510(k) Number (if known): K053405

Device Name: Antimicrobial Stopcock [or *Manifold*]

Indications for Use: Elcam *Antimicrobial Stopcock* [or *Manifold*] 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.

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The device is NOT intended to be used as a treatment for patient infections.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
Infection Control, Dental Devices
510(k) Number K053405

Concurrence of CDRH, Office of Device Evaluation (ODE)