K022895

OCT 18 2002

510(k) Summary for Elcam Stopcocks and Manifolds

1. SPONSOR

Elcam Plastic
Kibbutz BarAm
Merom Hagalil 13860
Israel

Contact Person: Shachar Regev

2. Device Name

Proprietary Name: Elcam Stopcocks and Manifolds
Common/Usual Name: Stopcocks and Manifolds
Classification Information:

Stopcocks have been classified as Class II devices under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Intravenous Stopcock Set	FMG	880.5440	General Hospital

3. PREDICATE DEVICES

Elcam Stopcocks and Manifolds are substantially equivalent to Elcam/RAM Development stopcocks, 510(k) No. K862691.

4. DEVICE DESCRIPTION

Elcam Stopcocks and Manifolds are composed of a body with two or three ports and a handle. Each port has either a male or female connector. Male connectors also include a nut for locking over the female connector of another component. A small amount of lubricant is applied between the stopcock body and handle. Elcam Stopcocks and Manifolds will be available in a wide variety of configurations for use according to the particular situation and the clinician's preference.

5. INTENDED USE

Elcam Stopcocks and Manifolds 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Elcam Stopcocks and Manifolds and Elcam/RAM Development stopcocks have the same indications for use. They have the same basic shape and both use luer fittings. Elcam Stopcocks and Manifolds have additional materials, are available sterile and have a wider range of inner diameters.

7. PERFORMANCE TESTING

Standard testing relating to function and stress-testing has been conducted on Elcam Stopcocks and Manifolds, including testing related to product label claims and testing comparing performance with existing products or materials.

A biocompatibility assessment was performed on the patient-contact and fluid-path materials of Elcam Stopcocks and Manifolds with satisfactory results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2002

Mr. Daniel J. Dillon
Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022895
Trade/Device Name: Elcam Stopcocks and Manifolds
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: August 30, 2002
Received: September 3, 2002

Dear Mr. Dillon:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022895

510(k) Number (if known):

Device Name: Elcam Stopcocks and Manifolds

Indications for Use:

Elcam Stopcocks and Manifolds 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: 022895

Prescription Use Y OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)