K060759
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JUN 29 2006

510(K) SUMMARY FOR ELCAM Y-CLICK CONNECTOR

DATE PREPARED: JUNE 21, 2006

Company Name: Elcam Medical ACAL

Contact Person:

Ms. Tali Hazan
RA Specialist
Telephone: +972-4-698-8875
Fax: +972-4-632-0777
E-mail: tali@elcam.co.il

Authorized US Agent:

Mr. Ehud Raivitz – CEO
Elcam Medical, Inc.
2 University Plaza, Suite 620,
Hackensack, NJ 07601, USA

Phone: 201-457-1120
Fax: 201-457-1125
E-mail: ehud@elcam-medical.com

Trade Name: Y-Click Connector

Classification name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Class: II
Panel identification: Cardiovascular devices
Product code: DTL
Regulation number: 872.4290

Predicate Devices: **EasyPass™ US Y-Connector Haemostatic Valve** from Millimed A/S, Roskilde, Denmark cleared under 510(k) no. **K042060**

Device description:

The *Y-Click connector* is an accessory that can be connected, by a standard male luer-lock, to any standard Angiographic catheter, up to 9 Fr guiding catheters. The device has a septum that prevents blood loss. Common guide-wires (in diameter of 0.014" to 0.038") can be introduced via the device (through the slit septum)

Elcam Medical

without bleeding due to the intra-catheter human arterial pressure. The septum can be opened to an unsealed position in order to enable introducing of various angioplasty devices (such as; balloons and stents). Unlike similar devices, The *Y-Click* can also be opened to a **semi unsealed position**. The semi unsealed position reduces the friction during catheter manipulation and makes the device more ergonomic and easy to use. The septum is opened to a **semi unsealed position** by one push of the cover (a "click" is heard). Pushing the cover twice (two "clicks" are heard) opens the device to an **unsealed position** (full **open position**). In order to return to a **closed position**, the *Y-Click*'s lever should be pressed once. A "click" is heard and the device returns to a **closed position**.

The injection of contrast media, saline flush and blood pressure monitoring can be performed through the Y side arm.

An illustration of the *Y-Click connector and its parts is presented in Sections 10 and 11 of this submission.*

Indications for Use:

The *Y-Click Connector* is a Y-connector Hemostatic Valve, which is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic and interventional devices used in angioplasty procedures such as; guide catheters, guide wires, balloons and stents. It is compatible with 9 Fr or smaller guide catheters and 0.014" – 0.038" diameter guide wires.

Substantial Equivalence:

The **Y-Click Connector** has the same intended use and the same principle of operation as the **EasyPass™** of Millimed A/S, cleared under 510(k) no. **K042060** and is therefore substantially equivalent to the predicate device.

Conclusion:

The evaluation of the Y-Click Connector does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

Elcam Medical, ACAL
c/o Ms. Tali Hazan
R.A. Specialist
Kibbutz BarAm
MP Merom HaGalil 13860
ISRAEL

Re: K060759
Y-Click Connector
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (Two)
Product Code: DTL
Dated: May 21, 2006
Received: May 24, 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) 276-0120. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060759

Device Name: Y-Click Connector .

Indications for Use:

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number