



JUN - 8 2012

**510(k) Summary**

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

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**Submitter Information**

Elcam Medical A.C.A.L.  
Kibbutz BarAm, M.P. Merom HaGalil, 13860, Israel  
Tel: (972) 4 6988120/1/2, Fax: (972) 4 6980777

**Submission contact person:**

Aharon Cohen  
Kibuz Bar Am 30889, Israel  
TEL: 972-4-6988324

**Device Classification**

**Proprietary Device Name:** Elcam Disposable integrated pressure transducer (DIPT)  
**Common name:** Disposable integrated pressure transducer (DIPT)  
**Product Code:** DRS  
**Classification Name:** Extravascular blood pressure transducer  
**Classification Regulation:** 21 CFR § 870.2850  
**Regulatory Class:** II

**Identification of Legally Marketed Predicate Devices**

Hospira Disposable integrated pressure transducer - K052828

**Device Description**

The disposable Transducer in an extravascular blood pressure transducer that convert mechanical changes in pressure into electrical current that can be input into a pressure monitor. The disposable Transducer consists of an extravascular pressure transducer module that interfaces between an intravascular catheter and pressure monitor. One of the major components that the transducer include is an integral flush valve and Luer connector that can connect a flashing fluid source to the intravascular catheter.

**Intended Use of Device**

The disposable Transducer is intended for direct measurement and monitoring of blood pressure. The disposable Transducer is intended for one time use.

Indications for the Disposable Integrated Pressure Transducer (DIPT) include:

- Direct arterial blood pressure monitoring – central and peripheral
- Pulmonary artery monitoring

- Venous pressure monitoring
- Left atrial monitoring when used with an air eliminator
- Cardiac catheterization

### **Safety & Effectiveness**

The proposed and predicate devices are similar in design, materials of construction, components, intended use and labeling.

Based on the performance results provided (including test results and clinical data) and the analysis of similarities and differences presented above, Elcam Medical believes that the proposed device safe & effectiveness is substantially equivalent to the predicate device without raising new safety and/or effectiveness issues.

### **Rational for Substantial Equivalency**

Elcam is the manufacturer of the Disposable integrated pressure transducer substantially equivalent to the predicate device and also the manufacture of the predicate device. Both products are the same products.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission

### **Substantial Equivalence Statement**

Based on the above, it is Elcam Medical's opinion that the proposed Elcam Disposable integrated pressure transducer is substantially equivalent in terms design principles, performance features and of safety & effectiveness to the legally cleared predicate device (K052828) referred to in chapter 4 of this 510(K) submission.



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

Elcam Medical A.C.A.L.  
c/o Mr. Aharon Cohen  
Regulation Affairs Manager  
M.P. Merom HaGalil  
Kibbutz BarAm, 13860  
Israel

JUN - 8 2012

Re: K120624  
Trade/Device Name: Elcam Disposable Integrated Pressure Transducer  
Regulation Number: 21 CFR 870.2850  
Regulation Name: Extravascular blood pressure transducer  
Regulatory Class: Class II (two)  
Product Code: DRS  
Dated: May 30, 2012  
Received: June 4, 2012

Dear Mr. Cohen:

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.

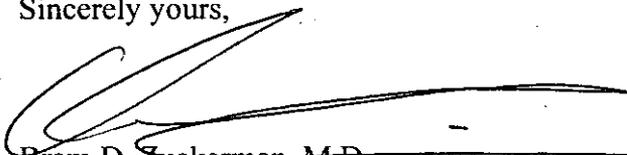
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K120624

### Indications for Use

510(k) Number (if known): K120624...

Device Name: Elcam Disposable Integrated Pressure Transducer

**Indications for Use:**

Elcam Disposable Integrated Pressure Transducer is intended for direct measurement and monitoring of blood pressure. The disposable Transducer is intended for single use only.

Indications for the Disposable Integrated Pressure Transducer (DIPT) include:

- Direct arterial blood pressure monitoring – central and peripheral
- Pulmonary artery monitoring
- Venous pressure monitoring
- Left atrial monitoring when used with an air eliminator
- Cardiac catheterization

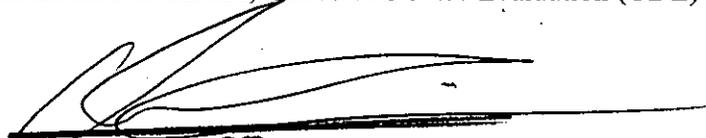
Prescription Use  X   
(Part 21 CFR 801 Subpart D)

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)



**(Division Sign-Off)**  
**Division of Cardiovascular Devices**

510(k) Number  K120624