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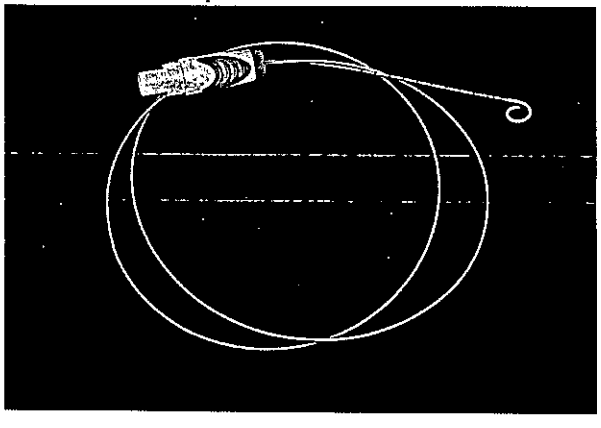
510(k) Summary:

510(k) Number: K112323

- **Organization No:** 211571
- **Establishment:** Millar Instruments, Inc.
- **Owner Name:** Huntly Millar
- **Address:** 6001-A Gulf Freeway, Houston, TX 77023
- **Phone:** 832-667-7000
- **Fax:** 832-667-7001
- **Registration No:** 1625382
- **Operations:** Specification Developer and Manufacturer of Mikro-Tip Catheter Transducers and Accessories for Clinical and Research purposes.
- **Contact Name:** Fatma Ali
- **Contact Title:** Director of Regulatory Affairs and Quality Assurance
- **Devices Name:** Cardia-Cath, Pressure Volume Catheter Transducer
- **Common Name/Model:** Cardia-Cath



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- **Classification:** Transducer, Pressure, Catheter Tip
- **Regulation:** Catheter Tip Pressure Transducer
- **Regulation Number:** 21 CFR 870-2870
- **Product Code :** DXO
- **Review Panel:** Cardiovascular
- **Device description:** The Cardia-Cath-Catheter is a disposable/single use, sterile pressure-volume catheter transducer that combines one or two pressure transducers and a series of electrodes mounted at various locations along the distal segment of the catheter body. It terminates in one electrical connection at the proximal end.
- **Intended use:** Cardia-Cath catheter is used to monitor combined pressure and electrical impedance (volume) in the cardiovascular system.
- **Labeling:** Labeling consists of IFU (P/N: 004-2181) and packaging label (P/N: CS-320-7251).
- **Risk Management**
    - Risk management report, project Code: 1-30-20, Project Name: Cardia-Cath
        - Report Summary:
            - Risk management has been conducted in accordance with ISO 14971:2007 to evaluate the modifications with regard to introduction of any new risk. Risk of using new configuration of the connector, off-the-shelf electrode material, and methodology of mounting the electrodes have been identified as unknown risk and shall be verified. Therefore, verification testing has been conducted. The following summary showed that the modified device passed all verification testing and it is substantially equivalent to the Millar legally marketed device, model SPC-550.

- **Verification testing and acceptance criteria**
    - Test Reports
        - BP-22 Verification test report reference VRP-2010-0423-02 VAL-181. The report shows successful execution of the predetermined test protocol addressing the requirements of the standard and following systematic procedures, SOP-2624, Design Verification Procedure and SOP-2626, Protocol and Report Writing.
            - Selected samples of the modified catheters were tested to the same specification as the legally marketed device as defined in its IFU. All catheters met the testing

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requirements and complied with BP-22 standard requirements. Two deviations from the legally marketed device specifications have been identified. These deviations have no impact on safety or efficacy. These deviations are:

- Temperature Error Band at Zero Pressure relaxed from 3.24 mmHg to 3.5 mmHG.
- Sensitivity Error Band" relaxed from 3.16% to 3.5%.

The modified device IFU includes the new values for the end user to be able to obtain same level of data accuracy. The final report has been reviewed and approved by qualified individuals.

- Transportation testing was performed on the fully packaged finished product of the modified device, Cardia-Cath by DDL. The test was performed in accordance with ASTM D4169-08. Samples passed all tests including bubble leak test and packaging integrity. DDL report No: 1009057 Rev. A is available for review. Then the catheters were tested for functionality to ensure no impact on the device functionality (safety and effectiveness) from transportation testing. This verification test was performed in accordance with Millar reference VRP-2010-0423-01 VAL-180.

- Biocompatibility
  - Biocompatibility testing was performed through Nelson Labs. Testing included all requirements per ISO 10993-1 for External communication device, circulating blood, contact duration A-Limited (<24hrs), which includes Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity, Systemic toxicity (acute), and Haemocompatibility. Samples of the legally marketed device and the modified device were sent to Nelson Laboratories to perform the required tests following GLP requirements. Nelson Labs analysis determined that the Cardia-Cath (modified device) was statistically similar, and therefore substantially equivalent, to the predicate (legally marketed) device, Model SPC-550. Test reports are available for FDA review, if required. The test reports are:
    - Modified ASTM Hemolysis (Direct Contact Method) GLP Report # 538955
    - Partial Thromboplastin time (PTT) test GLP Report # 538954
    - MEM Elution GLP Report # 538949
    - Complement Activation Test GLP Report # 538956
    - ISO Acute Systemic Injection Test GLP Report # 538952

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- Rabbit Pyrogen Test (Material Mediated)- ISO GLP Report # 538953
- ISO Interacutaneous Reactivity Test GLP Report # 538951
- Thrombogenicity Study in Dogs – ISO GLP Report # 538957
- ISO Guinea Pig Maximization Sensitization Test GLP Report # 538950

- Sterility
  - Method: EtO-Overkill
  - Validation of sterilization per ANSI/AAMI ISO 11135
  - Test report, Sterility test report # MI-0010 dated 04/20/11
  - Actual Sterility assurance level (SAL): 3.33 times more than what is required to achieve sterility ($1/10^6$)
  - Limulus Amebocyte Lysate test (LAL) for Pyrogen Free showed that the test article didn't significantly interfere with the lysate gel formation.
  - Packaging description:
    - Sterilant penetration and maintenance of sterility:
      - EtO Breathable materials (Tyvek)
  - Residuals:
    - Maximum level of residuals of EO 0.3096mg (<10mg)
    - Maximum level of Ethylene Cholorhydrin 0.1079mg (<5mg)
    - Per ANSI/AAMI/ISO 10993-7, Ethylene Glycol residuals are not included

- Accelerated aging (expiration date)
  - Reference Validation Report # VP-2010-0630-01, VAL-188, DHF820-0263, a 2-year accelerated aging test was performed by DDL on the actual modified device, Cardia-Cath. Cardia-Cath was subjected to accelerated aging testing in accordance with ASTM F1980-07; Guide for Accelerated Aging of Sterile Medical Device Packages. The test started on May 25, 2011 and was complete on August 08, 2011 (75 days). The tested samples were returned to Millar on August 10, 2011. Millar inspected the packages and the functionality of the Cardia-Cath. The result showed that Cardia-Cath passed the test criteria and is substantially equivalent to the predicate device, Model SPC-550.

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

OCT 1 8 2011

Millar Instruments, Inc.
c/o Ms. Fatma M. Ali
Director Regulatory Affairs and Quality Assurance
6001-A Gulf Freeway
Houston, TX 77023

Re: K112323
Trade/Device Name: Cardia-Cath
Regulatory Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: II (two)
Product Code: 74 DXO
Dated: September 15, 2011
Received: September 20, 2011

Dear Ms. Ali:

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 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" (21CFR 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

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1. Statement of indications for use

510(k) Number: K112323

Device Name: Cardia-Cath, Pressure-Volume (PV) Catheter

Indications for use: Monitoring combined pressure and electrical impedance (volume) in the cardiovascular system

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112323