DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 4, 2015

Biometrix Ltd.
Aviva Touati, Regulatory Affairs Manager
Kiryat Mada 4
Jerusalem, 91450
ISRAEL

Re: K151040
Trade/Device Name: Art-line Single Channel Blood Pressure System,
Art-line Double Channel Blood Pressure System,
Art-line Triple Channel Blood Pressure System,
Iap Monitoring Set With Disposable Transducer
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: April 17, 2015
Received: May 7, 2015

Dear Aviva Touati:

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.

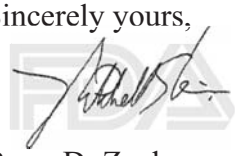
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151040

Device Name
Art-Line™ Disposable Pressure Transducer set

Indications for Use *(Describe)*

The Art-Line™ Disposable Pressure Transducer Set (Art-Line™ DPT) is intended for measuring and monitoring of the blood and/or intra-abdominal pressure of the critically ill patients.
The blood pressure sensing is carried out by converting of the hemodynamic waves from a patient's intravascular catheter, through the integrated pressure transducer/sensor, into electrical signals which can be displayed on a monitoring equipment. The intra-abdominal pressure sensing is carried out in the same manner, however by converting of the physiological waves from the patient's inflated bladder.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K151040

510(k) Summary

1. **Applicant information**
   a) Company address:
   Biometrix Ltd
   Kiryat Mada 4, 91450 Jerusalem
   Israel
   www.biometrixmedical.com
   b) Contact person: Aviva Touati, RA Manager
   E-mail: Aviva@biometrixmedical.com
   c) Additional Contact person: Zoya Lee, RA CO, Degania Silcione ltd.
   E-mail: Zoya@ds-il.com

2. **Device identification**
   a) Common name : Disposable Pressure Monitoring System
   b) Trade name : Art-Line™ Disposable Pressure Transducer set
   c) Classification Panel : 21CFR 870.2850
   d) Product code : DRS

3. **Predicate Devices**
   a) Transpac® III Disposable Straight Pressure, Hospira, Inc, 510(k) K061573
   b) Accutrans Disposable Pressure Monitoring System, Biosensors International, 510(k) K070710

4. **Device Description**
   The Art-Line™ Disposable Pressure Transducer (Art-Line™ DPT) set is a disposable pressure transducer device that interfaces between a catheter and a monitoring equipment by converting changes in pressure into electrical signals. The Art-Line™ DPT (see Table 1.) is offered in different configurations to fit physicians' needs: with one, two or three channel lines. Also it may be offered as a closed system which assist to prevent blood loss and minimize a cross contamination risk. The complete configuration may be pole or patient mounted. The set is sterile and non-pyrogenic.

Table 1. Description of Device modes.

No	Series Group	Description
1	AA	Art-Line™ Adult Single channel with colored stripe (red or blue) - for blood pressure sensing
2	AB	Art-Line™ Adult Single channel - for blood pressure sensing
3	AE	Art-Line™ Adult Double channel - for blood pressure sensing
4	AC	Art-Line™ Adult Triple channel - for blood pressure sensing
5	AI	Art-Line™ Single channel, closed system. There are modes for adult and pediatric use - for blood pressure sensing
6	AF	Art-Line™ Pediatric Single channel - for blood pressure sensing
7	AP and CA	Art-Line™ Intra-Abdominal Pressure (IAP) transducer set – for IAP sensing via inflated bladder.

5. Indication For Use.

The Art-Line™ Disposable Pressure Transducer Set (Art-Line™ DPT) is intended for measuring and monitoring of the blood and/or intra-abdominal pressure of the critically ill patients.

The blood pressure sensing is carried out by converting of the hemodynamic waves from a patient's intravascular catheter, through the integrated pressure transducer/sensor, into electrical signals which can be displayed on a monitoring equipment. The intra-abdominal pressure sensing is carried out in the same manner, however by converting of the physiological waves from the patient's inflated bladder.

The device is for single and short term use.

6. Summary of the Technological Characteristics of the Devices in relation to predicate device(s).

The subject Art line models have a similar intended use and design construction with the equivalent components as the predicated models. The safety and effectiveness of the subject device models have been assessed and discussed further in Section 7 below.

7. **Assessment of Performance Data used to justify Substantial Equivalence**

a) Functional performance tests were performed on the Art-Line™ DPT to evaluate the performance and the reliability of the transducer in accordance to recommended performance standards, IEC 60601-2-34 and ANSI/AAMI BP22-1994. Based on the test results which meet the acceptance criteria, the transducer is concluded to be safe and effective for its intended use.

b) Biocompatibility tests were performed in accordance to IS010993-1 Part 1: *Evaluation & Testing.* Based on the test results, the Biocompatibility tests were performed in accordance to IS010993-1 Part 1: *Evaluation &Testing.* Based on the test results, the Art-line – Fluid Pressure monitoring set is

biocompatible and safe for its intended use is biocompatible and safe for its intended use

8. Conclusion

The results of the Functional Performance Tests and Biocompatibility tests have demonstrated that the Art-Line™ Disposable Pressure Transducer Set is substantially equivalent to the predicate devices and is safe and effective for its intended use.