DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2017

Millar, Inc.
% Allison Komiyama
Principal Consultant
Acknowledge Regulatory Strategies
2834 Hawthorn St.
San Diego, California 92104

Re: K163376
Trade/Device Name: Mikro-Cath Pressure Catheter, Model 825-0101
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: February 6, 2017
Received: February 9, 2017

Dear Allison Komiyama:

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,

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)*
K163376

Device Name

Mikro-Cath Pressure Catheter, Model 825-0101

Indications for Use *(Describe)*

The Mikro-Cath Pressure Catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intracompartmental, and airway pressures in the human body. The catheter is used as a minimally invasive device under short term limited body contact (<24 hours).

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

X 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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510(k) Summary

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K163376

DATE PREPARED
February 6, 2017

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PROPRIETARY NAME OF SUBJECT DEVICE
Mikro-Cath Pressure Catheter, Model 825-0101

COMMON NAME
Transducer, Pressure, Catheter Tip

DEVICE CLASSIFICATION
Catheter tip pressure transducer
(21 CFR 870.2870, Product Code DXO, Class II)

PREMARKET REVIEW
ODE/DCD/CDDB
Cardiovascular Panel

INDICATIONS FOR USE
The Mikro-Cath Pressure Catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intracompartmental, and airway pressures in the human body. The catheter is used as a minimally invasive device under short term limited body contact (<24 hours).

DEVICE DESCRIPTION
The Mikro-Cath Pressure Catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intracompartmental, and airway pressures in the human body. A pressure sensor is mounted at the distal tip of the catheter. The proximal end terminates in a connector. The sensor produces

510(k) Summary

an electrical output signal which varies in direct proportion to the magnitude of sensed pressure or sound.

PREDICATE DEVICE IDENTIFICATION

The Mikro-Cath Pressure Catheter is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K093111	Mikro-Cath / Millar Instruments, Inc.	✓
K061573	Transpac III Disposable Straight Pressure Transducer (DSPT) / Hospira, Inc.	
K830909	Mikro-Tip Catheter Pressure Transducer / Millar Instruments, Inc.	

SUMMARY OF NON-CLINICAL AND CLINICAL TESTING

No FDA performance standards have been established for the Mikro-Cath Pressure Catheter. No additional testing was provided in this submission in order to demonstrate substantial equivalence.

EQUIVALENCE TO PREDICATE DEVICES

Millar believes that the Mikro-Cath Pressure Catheter is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has identical design and dimensions, and uses similar or identical materials as the device cleared in K093111. The patient contacting materials, mechanical characteristics, and electrical characteristics of the subject device have not changed from the predicate device cleared in K093111. The subject device has the same or similar indications for use as the devices cleared in K093111, K061573, and K830909.

CONCLUSION

The Mikro-Cath Pressure Catheter is considered substantially equivalent to the predicate devices based on identical technological characteristics. While the subject device has expanded indications (i.e. it may be used to measure intracompartmental and airway pressure), the subject device does not raise new issues of safety or efficacy compared to the predicate devices.