December 18, 2022

Toray Industries, Inc.
% Yuya Shizume
Manager
Toray Industries (America), Inc.
461 Fifth Avenue, 9th Floor
New York, New York 10017

Re: K220881
Trade/Device Name: Inoue Balloon A
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon aortic valvuloplasty catheter
Regulatory Class: Class II
Product Code: OZT
Dated: November 10, 2022
Received: November 14, 2022

Dear Mr. Shizume:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jaime Raben -S

Jaime Raben, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220881

Device Name
INOUE BALLOON A

Indications for Use *(Describe)*
INOUE BALLOON A is intended for balloon aortic valvuloplasty (BAV) in patients with aortic stenosis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Submission sponsor
Toray Industries, Inc.
1-1, Nihonbashi-muromachi 2-chome,
Chuo-ku, Tokyo 103-8666, JAPAN
Phone: +81-3-3245-8606
Fax: +81-3-3245-8612
Email: ra-global-md.toray.ug@mail.toray
Contact: Satoshi Kakuyama, General Manager, Global Development and Regulatory Affairs Dept.

Submission correspondent
Toray Industries (America), Inc.
461 Fifth Avenue, 9th Floor
New York, NY 10017
Phone: 212-922-3711
Fax: 212-972-4279
Email: medical.tam.mb@mail.toray
Contact: Shunsuke Kobayashi, Director, Life Science

Date Prepared: March 11, 2022

II. DEVICE

Name of Device: INOUE BALLOON™ A
Common or Usual Name: Balloon Aortic Valvuloplasty Catheter
Classification Name: Catheter, Balloon Aortic Valvuloplasty (21 CFR 870.1255)
Regulatory Class: II
Product Code: OZT

III. PREDICATE DEVICE

NuMED NuCLEUS and NuCLEUS-X BAV Catheters, K082776/DEN080015

IV. DEVICE DESCRIPTION

INOUE BALLOON^{TM} A is intended for the treatment of patients with aortic valvuloplasty (BAV). The device is transported over a guidewire as it is inserted through a percutaneous entry site and expanded with a predetermined amount of the diluted contrast medium by use of specified syringe with extension tube connected to the balloon inflation luer-lock hub. This results in the staged inflation of the balloon from hour-glass to barrel shape. The balloon is stretched and made thinner by pushing the inner tube in during passing thorough the introducer sheath. A radiopaque marker is provided for fluoroscopic positioning of the device across the valve.

V. INDICATIONS FOR USE

INOUE BALLOON^{TM} A is intended for balloon aortic valvuloplasty (BAV) in patients with aortic stenosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The INOUE BALLOON^{TM} A is substantially equivalent in both function and use to the predicate devices, NuMED NuCLEUS and NuCLEUS-X BAV Catheters (K082776/DEN080015).

The subject device has the same intended use as and has equivalent technology to the predicate device. The predicate device is a Class II legally marketed device.

The subject device has the same construction as the predicate device; that has a coaxial shaft construction with a distally mounted balloon. The balloon of the subject device consists of a complex of latex and the fiber mesh has semi-compliant characteristics which differs from non-compliant characteristics of the predicate device. Due to the semi-compliant balloon characteristics, the diameter of inflated balloon is controlled by the infusion volume. Since the balloon burst strength is almost the same as that of the predicate device, it can be said that the function of the subject device as a balloon catheter for aortic valve dilation is substantially equivalent to that of the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- Radio-detectability
- Surface
- Corrosion resistance
- Peak tensile force
- Freedom from leakage
- Hubs
- Designation of nominal size
- Diameter of the largest guidewire
- Sheath compatibility
- Balloon minimum burst strength test
- Balloon fatigue test for freedom from leakage and damage on inflation
- Balloon inflation and deflation times test
- Torquing
- Balloon preparation test
- Bending test
- Balloon over inflation test
- Catheter removal test
- Usability evaluation

In addition, the device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device.
The preclinical testing showed that the device meets specifications before and after aging indicating that the device is as safe and effective as the predicate device.

VIII. CONCLUSIONS

The INOUE BALLOON^{TM} A is substantially equivalent to the predicate devices (NuMed NuCLEUS and NuCLEUS-X BAV Catheters).