March 27, 2026

Terumo Corporation
Kirsten Steinmann
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue
Suite 320
Somerset, New Jersey 08873

Re: K252295
Trade/Device Name: Ryurei
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: July 23, 2025
Received: July 23, 2025

Dear Kirsten Steinmann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.03.27 16:30:01 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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)*
K252295

Device Name
Ryurei

Indications for Use *(Describe)*
Ryurei (1.5 mm) is indicated for:
• Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
• Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.

Ryurei (2.0–4.0 mm) is indicated for:
• Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
• Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.
• Balloon post-deployment expansion of balloon expandable stents (bare metal and drug-eluting).

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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"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

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared by: Kirsten Steinmann
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
Tel. (908) 381-5634

Prepared for: ***Owner/Operator***
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Date prepared: February 24, 2026

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	Ryurei
	Percutaneous Transluminal Coronary Angioplasty (PTCA)
Common Name:	Catheter
	Catheters, transluminal coronary angioplasty, percutaneous
Classification Name:	Cardiovascular
Classification Panel:	21 CFR 870.5100
Regulation:	LOX
Product Code:	Class II
Classification:	

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device(s) to which substantial equivalence is/are claimed is:

Predicate Device:

K180921 Sapphire II PRO Balloon Dilatation Catheter, manufactured by OrbusNeich Medical Trading Inc.

Reference Devices:

- K220629 Emerge Monorail PTCA Dilatation Catheter, manufactured by Boston Scientific
- K141025 Artimes Balloon Dilatation Catheter, manufactured by BrosMed Medical
- K141236 NC Emerge PTCA Dilatation Catheter by Boston Scientific Corporation
- K163372 RX Takeru Balloon Dilatation Catheter by Kaneka Corporation

D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) for Ryurei - PTCA Dilatation Catheter (RX) is being submitted for a new device for the purposes of establishing substantial equivalence to a legally marketed predicate device. The differences lie in the specifications, additional sizes, and the indication for balloon post-deployment expansion of balloon expandable stents.

E. INDICATIONS FOR USE (807.92(a)(5))

Ryurei (⌀1.5 mm) is indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
- Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.

Ryurei (⌀2.0–4.0 mm) is indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
- Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.
- Balloon post-deployment expansion of balloon expandable stents (bare metal and drug-eluting).

F. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

Ryurei, the subject of this 510(k), is substantially equivalent to the **Sapphire II Pro Balloon Dilatation Catheter** manufactured by OrbusNeich Medical.

The Ryurei is substantially equivalent to the predicate device, given that:

- It has the same intended use.
- It uses the same operating principle.
- It incorporates the same basic design/construction.
- It is sterilized by the same method (Ethylene Oxide).
- It uses the same fundamental scientific technology.
- Performance (Bench), Biocompatibility and Packaging integrity test data establishes the substantial equivalency to the predicate device.

In addition to the above-listed predicate, Terumo has identified the reference device **Emerge Monorail PTCA Dilatation Catheter** for the indication of balloon post-deployment expansion of balloon expandable stents (bare metal and drug-eluting).

A comparison of the technological characteristics is summarized in **Table 3** below.

Table 3: Summary of Comparative Information

Device Characteristic	**Subject Device:** Ryurei	**Predicate:** Sapphire II PRO Balloon Dilatation Catheter	**Reference:** Emerge Monorail PTCA Dilatation Catheters	**Reference:** Artimes Balloon Dilatation Catheter	**Reference:** NC EMERGE PTCA DILATATION CATHETER	**Reference:** RX Takeru Balloon Dilatation Catheter
Manufacturer	Terumo Corporation	OrbusNeich Medical	Boston Scientific	BrosMed Medical	Boston Scientific Corporation	Kaneka Corporation
Intended Use	For balloon dilatation in a coronary artery or bypass graft.	Same	Same	Same	Same	Same
Indications for Use	Ryurei (⌀1.50 mm) is indicated for: • Balloon **dilatation** of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of **improving myocardial perfusion**. • Balloon dilatation of a coronary artery occlusion for **the treatment of acute myocardial infarction**. Ryurei (⌀2.00–4.00 mm) is indicated for: • Balloon **dilatation** of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of **improving myocardial perfusion**. • Balloon dilatation of a coronary artery occlusion for **the treatment of acute myocardial infarction**. • Balloon **post-deployment expansion of balloon expandable stents** (bare metal and drug-eluting).	The Sapphire II Pro Balloon Dilatation Catheter (⌀1.0-1.25mm configurations) is indicated for: Balloon **pre-dilatation** of a stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of **improving myocardial perfusion**. The Sapphire II Pro Balloon Dilatation Catheter (⌀1.5-4.0mm configurations) is indicated for: Balloon **dilatation** of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of **improving myocardial perfusion**. Balloon **dilatation** of a coronary artery occlusion for **the treatment of acute myocardial infarction**. The Sapphire II Pro Balloon Dilatation is also indicated for: Percutaneous transluminal angioplasty in the peripheral vasculature, including renal, femoral, infra-popliteal, tibial, and peroneal arteries.	The Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis). The Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-5.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the **postdelivery expansion of balloon expandable stents** (bare metal and drug-eluting).	The Artimes Balloon Dilatation Catheter is indicated for: Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction	The NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patients with atherosclerosis. The NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters (balloon models 2.00 mm-5.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).	The RX Takeru PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion. This product (balloon models 2.0-5.0 mm) is also indicated for the post-delivery expansion of balloon expandable stents.
Operation Principle	Manual	Manual	Manual	Manual	Same	Same
Design / Construction	The tip of the catheter is equipped with a balloon inflatable to a specific diameter and length at recommended pressures.	Same	Same	Same	Same	Same
	One or two radiopaque markers inside the balloon.	Same	Same	Same	Same	Same
	On the shaft, there are two depth markers.	Same	Same	Same	Same	Same
	Double-lumen structure, with a guidewire lumen and an inflation lumen.	Same	Same	Same	Same	Same

Device Characteristic	**Subject Device:** Ryurei	**Predicate:** Sapphire II PRO Balloon Dilatation Catheter	**Reference:** Emerge Monorail PTCA Dilatation Catheters	**Reference:** Artimes Balloon Dilatation Catheter	**Reference:** NC EMERGE PTCA DILATATION CATHETER	**Reference:** RX Takeru Balloon Dilatation Catheter
	A hub is attached to the balloon for inflation/deflation.	Same	Same	Same	Same	Same
	The surface of catheter is coated with hydrophilic polymer coating.	Same	Same	Same	Same	Same
Materials	• Nylon 12-polytetramethylene glycol copolymer • Nylon 12 • Denatured polyethylene • Stainless steel • Dimethyl acrylamide-glycidyl methacrylate copolymer • Platinum-Iridium • Polycarbonate • Urethane acrylate resin • Pigment	Information not publicly available.	Information not publicly available.	Information not publicly available.	Information not publicly available.	Information not publicly available.
	Presence of hydrophilic coating: Yes	Yes Hydrophilic coating	Yes Hydrophilic coating	Yes Hydrophilic coating	Yes Hydrophilic coating	Yes Hydrophilic coating
Package Materials	• Individual package -Individual package Film: Polyethylene-polyester laminated film Paper: Polyethylene -Individual package Label: Paper • Unit box -Unit box: Coated cardboard -Unit box Label: Paper • Shipping carton -Shipping carton: Corrugated cardboard -Shipping carton Label: Paper	Information not publicly available.	Information not publicly available.	Information not publicly available.	Information not publicly available.	Information not publicly available.
Package	Individual package on which the product label and the peel-off labels are attached 1 unit per package.	Same	Same	Same	Same	Same
Specifications	Catheter effective length: 145 cm	Catheter effective length: 140 cm	Catheter effective length: 144 cm	Catheter effective length: 140 cm	Catheter effective length: 143 cm	Catheter effective length: 145 cm
	Balloon length: 5, 10, 15, 20, 30, 40 mm	Balloon length: 5, 8, 10, 12, 15, 20, 30 mm	Balloon length: 8, 12, 15, 20, 30, 40 mm	Balloon length: 5, 8, 10, 12, 15, 20, 25, 30 mm	Balloon length: 6, 8, 12, 15, 20, 30 mm	Balloon length: 6, 8, 12, 15, 20 mm
	Balloon diameter: 1.5, 2.0, 2.25, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0 mm	Balloon diameter: 1.0, 1.25, 1.5, 1.75, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 4.0 mm	Balloon diameter: 1.2, 1.5, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0, 4.5, 5.0 mm	Balloon diameter: 1.0, 1.25, 1.5, 1.75, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0 mm	Balloon diameter: 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.0 mm	Balloon diameter: 1.5, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0 mm
	Nominal pressure: 6 atm (608 kPa)	Same	Same	Same	Nominal pressure: 12 atm (1215 kPa)	Same
	Rated burst pressure: ⌀1.50–3.00 mm: 14 atm (1419 kPa) ⌀3.25–4.00 mm: 12 atm (1216 kPa)	Rated burst pressure: 14 atm (1419 kPa)	Rated burst pressure: ⌀1.2 mm: 18 atm (1824 kPa) ⌀1.5–3.25 mm: 14 atm (1419 kPa) ⌀3.5–5.0 mm: 12 atm (1216 kPa)	Rated burst pressure: 14 atm (1419 kPa)	Rated burst pressure: ⌀2.0–4.0 mm: 20 atm (2024 kPa) ⌀4.5–6.0 mm: 18 atm (1824 kPa)	Rated burst pressure: 14 atm (1419 kPa)

Device Characteristic	**Subject Device:** Ryurei	**Predicate:** Sapphire II PRO Balloon Dilatation Catheter	**Reference:** Emerge Monorail PTCA Dilatation Catheters	**Reference:** Artimes Balloon Dilatation Catheter	**Reference:** NC EMERGE PTCA DILATATION CATHETER	**Reference:** RX Takeru Balloon Dilatation Catheter
	Radiopaque marker type: ⌀1.50 mm: Single marker ⌀2.00–4.00 mm: Double marker	Radiopaque marker type: ⌀1.0–1.5 mm: Single marker ⌀1.75–4.0 mm: Double marker	Radiopaque marker type: ⌀1.2–1.5 mm: Single marker ⌀2.0–5.0 mm: Double marker	Radiopaque marker type: ⌀1.0–1.75 mm: Single marker ⌀2.0–4.0 mm: Double marker	Radiopaque marker type: Double marker	Radiopaque marker type: ⌀1.5 mm: Single marker ⌀2.0–5.0 mm: Double marker
Sterilization	Ethylene oxide	Same	Same	Same	Same	Same
Shelf Life	36 months after sterilization	Information not publicly available.	24 months after sterilization	Information not publicly available.	Information not publicly available.	36 months after sterilization

G. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the operability and functionality of Ryurei throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. Except for the Radio-detectability and Simulated Use tests, which were only performed on non- aged samples, the following performance tests were conducted on both non-aged and aged samples.

The below table provides a list of performance tests that were performed on Ryurei.

Test Item
Dimensional Verification
Balloon Rated Burst Pressure
Balloon Fatigue (Repeat Balloon Inflations)
Balloon Compliance (Diameter vs. Pressure)
Balloon Inflation and Deflation Time
Catheter Bond Strength
Tip Pull Test
Flexibility and Kink Test
Torque Strength
Radiopacity
Coating Integrity
Particulate Evaluation
Balloon Rated Burst Pressure (in Stent)
Balloon Fatigue (Repeat Balloon Inflations; in Stent)
Surface
Corrosion Resistance
Hub
Sliding resistance
Simulated use test (Balloon Preparation, Deployment and Retraction)

Biocompatibility

In accordance with ISO 10993-1, the Ryurei is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). The finished device's blood/body contacting parts were tested in accordance with the tests recommended in the FDA Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." Screening tests were performed on aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing

demonstrate that the device is biocompatible throughout the shelf life of the product.

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reaction
Systemic Toxicity (Acute)
Pyrogenicity
Hemolysis
Complement Activation
In vivo Thrombogenicity
Physicochemical
FT-IR
Aged (3 years), sterile, whole device
Cytotoxicity
Hemocompatibility
Physicochemical
FT-IR

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014/Amd 1:2018, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*, to provide a Sterility Assurance Level (SAL) of 10^{-6}.

H. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

I. CONCLUSION (807.92(b)(3))

In summary, Ryurei, subject of this 510(k), is substantially equivalent in its intended use/, technology/principal of operation, materials, and performance to the Sapphire II Pro Balloon Dilatation Catheter manufactured by OrbusNeich Medical Trading Inc.