

Review Summary

September 15, 2026

Pharmaceuticals and Medical Devices Agency

The following is the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Instrument & apparatus 51
Term name	:	Catheter for balloon dilation angioplasty
Brand name	:	Ranger Drug-Coated Balloon Catheter
Applicant	:	Boston Scientific Japan K.K.
Date of application	:	November 26, 2025
Date of approval	:	June 17, 2026
Application classification	:	☐ New medical device ☒ Improved medical device (with clinical data) ☐ Improved medical device (without clinical data)
New approval / partial Change	:	☐ New approval ☒ Partial change
Review category	:	☒ Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐ Cardiopulmonary Circulation ☐ Dentistry and Oral Medicine ☐ Gastroenterology, Genitourinary, and Reproductive Medicine ☐ Ophthalmology and Otorhinolaryngology ☐ Orthopedic and Plastic Surgery ☐ Robotics, IoT, and other devices (not classified as other categories) ☐ Program D1 ☐ Program D2
Items warranting special mention	:	☐ Designated as medical devices with high medical need ☐ Designated as specific-usage medical device ☐ Application in accordance with conditional early approval system for medical devices (Type 1) ☐ Application in accordance with conditional early approval system for

medical devices (Type 2: “Physical operation of items’ extrapolative and inclusive approval” (Phoenix))

☐ Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐ Application in accordance with “Improvement design within approval for timely evaluation and notice” (IDATEN)

☐ Designated as orphan medical device

☐ Application in accordance with the 0929 notification

☐ Other ()

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

This product is a catheter for balloon dilatation angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or non-stented restenotic lesions in the superficial femoral or proximal popliteal arteries (Approval No. 30300BZX00033000). The balloon surface of this product is coated with paclitaxel as a drug. The purpose of this application is to change the target maximum lesion length from 180 mm to 340 mm. There is no change of this product itself in this application.

(2) Non-clinical data

The following non-clinical data were submitted (data items were based on applicant submission data).

- Safety study : A GLP safety study of drug

(3) Clinical data

The applicant submitted the analysis results from the ELEGANCE registry (hereinafter referred to as "the registry") conducted overseas in patients with long lesion length (greater than 180 mm) for which this product was used. The outline of the submitted data is as follows (with reference to the "Clinical Results" section of the package insert and adjusted as appropriate).

The registry is a global multi-center, prospective, non-randomized, open-label, post-marketing registry designed to collect real-world data and is being conducted throughout North America, Europe and Asia Pacific in the patients using commercially available Boston Scientific Corporation drug-eluting devices (Eluvia Drug-Eluting Vascular Stent System and/or Ranger Drug-Coated Balloon Catheter).

Of these, 228 patients (239 lesions) from 38 medical institutions with de novo or non-stented restenotic lesions with a length of more than 180 mm in the superficial femoral or proximal popliteal arteries were included in the analysis for the efficacy and safety of this product.

The primary patency rate at 12-months post-procedure, (defined as vascular patency by duplex ultrasonography and no clinically-driven target lesion revascularization) was 71.9% for each lesion (110 of 153 lesions) and 70.3% for each subject (102 of 145 subjects).

The major adverse events rate at 12-months post-procedure (defined as all-cause mortality, target limb major amputation, and target lesion revascularization; hereinafter referred to as "MAE") was 18.5% (40 of 216 subjects). Of these, all-causes of death was 8.3% (18 of 216 subjects), target limb major amputation was 3.2% (7 of 216 subjects), and target lesion revascularization was 9.3% (20 of 216 subjects).

Subgroup analysis by lesion length revealed that the primary patency rate at 12-months post-procedure was 71.1% (64 of 90 lesions) and 68.7% (57 of 83 subjects) in the >180-240 mm group, 79.4% (27 of 34 lesions) and 78.8% (26 of 33 subjects) in the 241-300 mm group, and 83.3% (5 of 6 lesions, 5 of 6 subjects) in the

301-340 mm group. The MAE rate at 12-months was 21.8% (26 of 119 subjects) in the >180-240 mm group, 12.0% (6 of 50 subjects) in the 241-300 mm group, and 15.4% (2 of 13 subjects) in the 301-340 mm group.

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the partial change could be approved.

<Intended use> *Changes are indicated by underlining.

This product is used for percutaneous transluminal angioplasty (PTA) of de novo or non-stented restenotic lesions up to 340 mm in length located in superficial femoral and/or proximal popliteal arteries with reference vessel diameters of 4 mm to 7 mm.