

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 7
Term name	:	Aortic stent graft
Brand name	:	VALIANT Thoracic Stent Graft System
Applicant	:	Medtronic Japan Co., Ltd.
Date of application	:	November 19, 2025
Date of approval	:	June 8, 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

The product is an aortic stent graft intended for intravascular treatment of thoracic aortic diseases. It has been approved to date for the indication of treatment of aortic aneurysm or Stanford type B aortic dissection accompanied by complications, including dissecting aortic aneurysm, in the descending thoracic aorta (Approval No. 22400BZX00124000). The application was submitted to add the indication for traumatic aortic injury.

(2) Non-clinical data

The following non-clinical data were submitted.

- Usability: Materials demonstrating conformity with the usability engineering process IEC 62366-1:2015+AMD1:2020

(3) Clinical data

The applicant submitted a clinical evaluation report summarizing literature and other information related to the effectiveness and safety of the product for traumatic aortic injury in the descending thoracic aorta. The outline of the results of the overseas clinical trial (RESCUE study) that served as the core of this clinical evaluation report is provided below (with reference to the “Clinical Results” section of the package insert and table numbers adjusted as appropriate).

The RESCUE study was a prospective, non-randomized, multicenter trial conducted to evaluate the clinical performance of the product in the treatment of traumatic aortic injury, and 50 cases were enrolled in the United States and Canada. The primary endpoint was all-cause mortality within 30 days after the initial procedure. The results are shown in Table 1. The technical success rate was 100%, and

vascular access, delivery, and deployment were successful in all cases. There were no reinterventions related to endovascular treatment and no conversions to open thoracic surgery. No endoleaks were observed in core laboratory evaluations at the 1-month, 6-month, and 12-month follow-up time points. A summary of serious adverse events (SAEs) during the 5-year follow-up is shown in Table2.

Table 1: Primary endpoint (all-cause mortality within 30 days after procedure)

Primary endpoint	% (cases)
All-cause mortality within 30 days	8.0% (4/50)

Table 2: Summary of serious adverse events (SAEs) (site-reported)

	% (cases)					
	0–30 days	31–365 days	366–731 days	732–1096 days	1097–1461 days	1462–1826 days
Total	18.0% (9/50)	6.5% (3/46)	0.0% (0/39)	5.6% (2/36)	0.0% (0/32)	3.2% (1/31)
Cardiac disorders	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	3.2% (1/31)
Arrhythmia	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Myocardial infarction	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	3.2% (1/31)
Gastrointestinal disorders	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	2.8% (1/36)	0.0% (0/32)	0.0% (0/31)
Peritoneal haemorrhage	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	2.8% (1/36)	0.0% (0/32)	0.0% (0/31)
Infections and infestations	0.0% (0/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Infection	0.0% (0/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Injury, poisoning and procedural complications	6.0% (3/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Multiple injuries	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Traumatic brain injury	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Venous injury	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Musculoskeletal and connective tissue disorders	0.0% (0/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Pain in extremity	0.0% (0/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Nervous system disorders	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	2.8% (1/36)	0.0% (0/32)	0.0% (0/31)
Anoxic encephalopathy	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Cerebrovascular accident	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Convulsion	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	2.8% (1/36)	0.0% (0/32)	0.0% (0/31)
Paraparesis	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Paraplegia	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Spinal cord ischaemia	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Stroke	0.0% (0/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Respiratory, thoracic and mediastinal disorders	4.0% (2/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Haemothorax	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Respiratory failure	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Vascular disorders	6.0% (3/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Femoral artery dissection	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Intermittent claudication	2.0% (1/50)	0.0% (0/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)
Peripheral ischaemia	2.0% (1/50)	2.2% (1/46)	0.0% (0/39)	0.0% (0/36)	0.0% (0/32)	0.0% (0/31)

2. Review results

PMDA concluded that the application based on the clinical evaluation report is acceptable because the effectiveness and safety of the product are considered to be publicly known in medical and pharmaceutical fields. As a result of the review of the submitted clinical evaluation report, PMDA concluded that the partial change could be approved with the following intended use shown below with the following approval conditions.

<Intended Use> (Underlined text indicates revised portions)

This product is intended for use in the treatment of patients with aortic aneurysm, traumatic aortic injury or Stanford type B aortic dissection accompanied by complications refractory to medical therapy (including dissecting aortic aneurysm) in the descending thoracic aorta, who meet all of the following anatomical requirements.

- The iliac artery or femoral artery is suitable in size, morphology, etc., for the vascular access approach, insertion of the delivery system, and use of various concomitant catheters.
- The diameter of the non-aneurysmal aorta is 18 to 42 mm for aortic aneurysm, 18 to 44 mm for traumatic aortic injury, and 20 to 44 mm for aortic dissection.
- For aortic aneurysm, the non-aneurysmal vessel neck length on both the proximal and distal sides is at least 20 mm. For traumatic aortic injury and aortic dissection, the landing zone proximal to the main entry tear is at least 20 mm.

In addition, the proximal end of the covered portion of the stent graft must not involve the origin of the left common carotid artery.

<Conditions for Approval >

1. The applicant is required to take necessary measures to ensure that the product is used by physicians who have sufficient understanding of the effectiveness and safety of the product and sufficient knowledge and experience regarding procedures, etc., through training on endovascular treatment using the product for thoracic aortic treatment, etc.
2. The applicant is required to take necessary measures to ensure that the product is used at medical institutions that have a system in place to perform emergency prosthetic vascular replacement for thoracic aortic treatment.