Review Summary

May 19, 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	:	GORE TAG Thoracic Branch Endoprosthesis
Applicant	:	W. L. Gore & Associates G.K.
Date of application	:	Jun 25, 2025
Date of approval	:	March 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

The product is an aortic stent graft intended for intravascular treatment of thoracic aortic diseases. It was approved on November 27, 2024, for the indication of treatment of thoracic descending aorta diseases (Approval No. 30600BZX00248000). The application was submitted to add the indication for use of thoracic aortic aneurysm of the aortic arch; traumatic thoracic aortic injury of the aortic arch; Stanford type B aortic dissection accompanied by complications refractory to medical therapy (including dissecting aortic aneurysm) involving the aortic arch; and Stanford type A aortic dissection accompanied by complications refractory to medical therapy following surgical repair, involving the aortic arch and the descending thoracic aorta. An expert discussion was held to ask opinions on the effectiveness and safety of the product, as well as post-marketing safety measures.

(2) Non-clinical data

As this application did not involve any changes to the product itself, the submission of non-clinical data was omitted.

(3) Clinical data

The applicant submitted the results of a global multicenter clinical trial conducted in the United States and Japan for the additional indications. An outline of the submitted data is provided below (with reference to the "Clinical Results" section of the package insert and table numbers adjusted as appropriate).

The SSB 11-02 study, which was conducted to evaluate the effectiveness and safety of the product in the treatment of lesions of the aortic arch and descending thoracic aorta, was a prospective, non-randomized, multicenter trial.

The Zone 0/1 group consisted of three cohorts (aneurysm, dissection, and other isolated lesions), in which 52 aneurysm cases, 24 dissection cases, and 3 other isolated lesion cases were enrolled. The primary endpoint for the Zone 0/1 group was a composite endpoint evaluated from enrollment to 1 month post-procedure, consisting of the following components:

- Initiation of the index treatment following the debranching procedure
- Technical success of the investigational device
- Absence of the following events: aortic rupture; lesion-related death; disabling stroke; permanent paraplegia; permanent paraparesis; new onset renal failure requiring permanent dialysis; and unplanned additional surgical or endovascular intervention after the index treatment related to the investigational device, procedure, or removal of the delivery system

1) Zone 0/1 Group

The results of the Zone 0/1 group represent outcomes in patients at high risk for surgical repair.

① Zone 0/1 Aneurysm Cohort

In the Zone 0/1 aneurysm cohort, the primary endpoint success rate was 74.5% at 1 month post-procedure, and the lower limit of the 95% confidence interval was 61.9%, achieving the performance goal (60%). At 1 year post-procedure, the primary endpoint success rate in the Zone 0/1 aneurysm cohort was 72.7%, with a lower limit of the 95% confidence interval of 59.6%. The event rate of disabling stroke was 12.0% at 1 month post-procedure. Among patients in the Zone 0/1 aneurysm cohort whose proximal landing zone was a synthetic vascular graft (7 cases), the primary endpoint success rate at 1 year post-procedure was 50%.

Serious adverse events observed in the Zone 0/1 aneurysm cohort are summarized in Table 1.

Table 1: Serious adverse events (Zone 0/1 Aneurysm Cohort)

	During Revascularization	During Procedure	1 Month	6 Months	1 Year	Total
Number of subjects	50	50	49	47	44	50
Number of subjects with events	9 (18.0%)	16 (32.0%)	12 (24.5%)	10 (21.3%)	6 (13.6%)	41 (82.0%)
Infections and infestations	0 (0%)	0 (0%)	1 (2.0%)	4 (8.5%)	3 (6.8%)	12 (24.0%)
Benign, malignant and unspecified neoplasms (including cysts and polyps)	0 (0%)	0 (0%)	0 (0%)	1 (2.1%)	0 (0%)	3 (6.0%)
Blood and lymphatic system disorders	0 (0%)	0 (0%)	1 (2.0%)	1 (2.1%)	0 (0%)	2 (4.0%)
Metabolism and nutrition disorders	0 (0%)	0 (0%)	1 (2.0%)	0 (0%)	0 (0%)	1 (2.0%)
Psychiatric disorders	0 (0%)	0 (0%)	0 (0%)	1 (2.1%)	0 (0%)	1 (2.0%)
Nervous system disorders	2 (4.0%)	5 (10.0%)	3 (6.1%)	3 (6.4%)	1 (2.3%)	11 (22.0%)
Eye disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.0%)
Cardiac disorders	1 (2.0%)	2 (4.0%)	4 (8.2%)	2 (4.3%)	2 (4.5%)	14 (28.0%)
Vascular disorders	2 (4.0%)	6 (12.0%)	3 (6.1%)	2 (4.3%)	0 (0%)	11 (22.0%)
Respiratory, thoracic and mediastinal disorders	1 (2.0%)	3 (6.0%)	1 (2.0%)	3 (6.4%)	0 (0%)	11 (22.0%)
Gastrointestinal disorders	0 (0%)	0 (0%)	2 (4.1%)	1 (2.1%)	0 (0%)	5 (10.0%)
Musculoskeletal and connective tissue disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (4.0%)
Renal and urinary disorders	0 (0%)	1 (2.0%)	1 (2.0%)	1 (2.1%)	1 (2.3%)	5 (10.0%)
General disorders and administration site conditions	0 (0%)	1 (2.0%)	1 (2.0%)	2 (4.3%)	1 (2.3%)	10 (20.0%)
Injury, poisoning and procedural complications	5 (10.0%)	2 (4.0%)	1 (2.0%)	1 (2.1%)	1 (2.3%)	10 (20.0%)

Follow-up period: During Procedure (Day 0), 1 Month (Days 1–30), 6 Months (Days 31–182), 1 Year (Days 183–365), and Total (from the time of revascularization to Day 2006).

② Zone 0/1 Dissection Cohort

Among the Zone 0/1 dissection cohort, the primary endpoint success rate at 1 year post-procedure was 62.5% in patients with chronic Stanford type B dissection accompanied by complications (8 cases). The incidence of disabling stroke was 0% at 1 month post-procedure.

Serious adverse events observed in the Zone 0/1 dissection cohort are shown in Table 2.

Table 2: Serious Adverse Events (Chronic Stanford Type B Dissection with Complications)

	During Revascularization	During Procedure	1 Month	6 Months	1 Year	Total
Number of subjects	8	8	8	7	6	8
Number of subjects with events	2 (25.0%)	0 (0%)	3 (37.5%)	2 (28.6%)	2 (33.3%)	7 (87.5%)
Infections and infestations	1 (12.5%)	-	2 (25.0%)	1 (14.3%)	0 (0%)	3 (37.5%)
Blood and lymphatic system disorders	0 (0%)	-	0 (0%)	1 (14.3%)	0 (0%)	1 (12.5%)
Metabolism and nutrition disorders	1 (12.5%)	-	0 (0%)	0 (0%)	0 (0%)	2 (25.0%)
Cardiac disorders	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	2 (25.0%)
Vascular disorders	0 (0%)	-	1 (12.5%)	1 (14.3%)	0 (0%)	2 (25.0%)
Gastrointestinal disorders	0 (0%)	-	0 (0%)	1 (14.3%)	1 (16.7%)	1 (12.5%)
Hepatobiliary disorders	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	1 (12.5%)
Renal and urinary disorders	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	1 (12.5%)
General disorders and administration site conditions	0 (0%)	-	1 (12.5%)	0 (0%)	1 (16.7%)	3 (37.5%)
Injury, poisoning and procedural complications	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	1 (12.5%)

Follow-up period: During procedure (Day 0), 1 Month (Days 1–30), 6 Months (Days 31–182), 1 Year (Days 183–365), and Total (from the time of revascularization to Day 2006).

③ Zone 0/1 Other Isolated Lesion Cohort

From the Zone 0/1 other isolated lesion cohort, results for penetrating aortic ulcer (1 case) were presented (Table 3). The primary endpoint success rate for penetrating aortic ulcer was 100.0% at 1 year post-procedure. The incidence of disabling stroke was 0% at 1 month post-procedure.

Table 3: Serious Adverse Events (Penetrating Aortic Ulcer)

	During Revascularization	During Procedure	1 Month	6 Months	1 Year	Total
Number of subjects	1	1	1	1	1	1
Number of subjects with events	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100.0%)
Eye disorders	-	-	-	-	-	1 (100.0%)
General disorders and administration site conditions	-	-	-	-	-	1 (100.0%)

Follow-up period: during the procedure (Day 0), 1 month (Days 1–30), 6 months (Days 31–182), 1 year (Days 183–365), and total (from the time of revascularization to Day 2006).

2) Zone 0/1/2 Residual Dissection with Complications Group

Among the Zone 0/1/2 dissection cohort, the primary endpoint success rate at 1 year post-procedure was 86.5% in patients with residual dissection accompanied by complications (39 cases). The incidence of disabling stroke was 2.6% at 1 month post-procedure.

Serious adverse events observed in patients with residual dissection accompanied by complications in the Zone 0/1/2 dissection cohort are shown in Tables 4 and 5.

Table 4: Serious Adverse Events (Residual Dissection with Complications, Zone 0/1)

	During Revascularization	During Procedure	1 Month	6 Months	1 Year	Total
Number of subjects	14	14	14	14	14	14
Number of subjects with events	2 (14.3%)	5 (35.7%)	5 (35.7%)	3 (21.4%)	4 (28.6%)	11 (78.6%)
Infections and infestations	0 (0%)	0 (0%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	4 (28.6%)
Psychiatric disorders	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)	0 (0%)	1 (7.1%)
Cardiac disorders	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)	0 (0%)	3 (21.4%)
Vascular disorders	0 (0%)	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	3 (21.4%)
Respiratory, thoracic and mediastinal disorders	1 (7.1%)	2 (14.3%)	3 (21.4%)	1 (7.1%)	2 (14.3%)	5 (35.7%)
Gastrointestinal disorders	0 (0%)	1 (7.1%)	1 (7.1%)	0 (0%)	1 (7.1%)	4 (28.6%)
Musculoskeletal and connective tissue disorders	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)	0 (0%)	1 (7.1%)
Renal and urinary disorders	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)	0 (0%)	1 (7.1%)
General disorders and administration site conditions	0 (0%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	0 (0%)	2 (14.3%)
Injury, poisoning and procedural complications	1 (7.1%)	2 (14.3%)	1 (7.1%)	0 (0%)	0 (0%)	3 (21.4%)

Follow-up period: During procedure (Day 0), 1 Month (Days 1–30), 6 Months (Days 31–182), 1 Year (Days 183–365), and Total (from the time of revascularization to Day 2006).

Table 5: Serious Adverse Events (Residual Dissection with Complications, Zone 2)

	During Procedure	1 Month	6 Months	1 Year	Total
Number of subjects	25	25	24	23	25
Number of subjects with events	3 (12.0%)	8 (32.0%)	6 (25.0%)	4 (17.4%)	18 (72.0%)
Infections and infestations	0 (0%)	2 (8.0%)	2 (8.3%)	2 (8.7%)	8 (32.0%)
Benign, malignant and unspecified neoplasms (including cysts and polyps))	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8.0%)
Blood and lymphatic system disorders	0 (0%)	0 (0%)	0 (0%)	2 (8.7%)	3 (12.0%)
Metabolism and nutrition disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4.0%)
Psychiatric disorders	2 (8.0%)	1 (4.0%)	3 (12.5%)	1 (4.3%)	9 (36.0%)
Nervous system disorders	0 (0%)	2 (8.0%)	3 (12.5%)	0 (0%)	7 (28.0%)
Vascular disorders	1 (4.0%)	1 (4.0%)	0 (0%)	3 (13.0%)	6 (24.0%)

Respiratory, thoracic and mediastinal disorders	0 (0%)	1 (4.0%)	1 (4.2%)	1 (4.3%)	4 (16.0%)
Gastrointestinal disorders	0 (0%)	1 (4.0%)	0 (0%)	0 (0%)	4 (16.0%)
Musculoskeletal and connective tissue disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8.0%)
Renal and urinary disorders	0 (0%)	1 (4.0%)	0 (0%)	0 (0%)	6 (24.0%)
General disorders and administration site conditions	0 (0%)	1 (4.0%)	0 (0%)	0 (0%)	3 (12.0%)
Injury, poisoning and procedural complications	1 (4.0%)	2 (8.0%)	0 (0%)	0 (0%)	6 (24.0%)

Follow-up period: During procedure (Day 0), 1 Month (Days 1–30), 6 Months (Days 31–182), 1 Year (Days 183–365), and Total (Days 0–2006).

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the partial change could be approved for the following intended use shown below with the following approval conditions. This product is designated as a medical device subject to a use-results survey. The use-results survey period should be 9 years and 3 months.

<Intended use> (Underlined text indicates revised portions)

The GORE TAG Thoracic Branch Endoprosthesis is intended for use, among patients who meet all anatomical requirements, for the treatment of the following diseases involving lesions of the aortic arch and descending thoracic aorta, while preserving blood flow to the aortic arch branch vessels:

- Thoracic aortic aneurysm
- Traumatic thoracic aortic injury
- Stanford type A (post-surgical repair) and type B aortic dissection accompanied by complications refractory to medical therapy (including dissecting aortic aneurysm)

In some cases, the product may be used in combination with designated stent grafts whose effectiveness and safety have been confirmed.

<Conditions for Approval> (Underlined text indicates revised portions)

1. The applicant is required to take necessary measures, in cooperation with relevant academic societies, to ensure that the product is used by physicians with sufficient knowledge and experience in endovascular repair of thoracic aortic diseases at medical institutions able to provide treatment of possible complications of endovascular stent graft repair.
2. The applicant is required to take necessary measures, in cooperation with relevant academic societies, to ensure that the product is used only for the indication by qualified physicians (i.e., those who meet the criteria specified in Conditions for Approval 1) who, through training, etc., have acquired sufficient skills in maneuvering the product and sufficient knowledge of complications of the procedures .
3. The applicant is required to conduct a post-marketing survey covering all patients treated with the

product until data are gathered from a certain number of cases with aortic arch lesions, including traumatic thoracic aortic injury and Stanford type A (post surgical repair) and type B aortic dissection, to submit annual reports on the results of long-term outcome analyses to the Pharmaceuticals and Medical Devices Agency, and to take appropriate measures as necessary.