Review Summary

July 23, 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, Organ Function Replacement Device
Term name	:	Transcatheter porcine pericardial valve
Brand name	:	Evolut FX+ system
Applicant	:	Medtronic Japan Co., Ltd.
Date of application	:	December 23, 2025
Date of approval	:	May 14, 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 prosthetic cardiac valve used for transcatheter cardiac valve implantation. This product has been approved for the treatment of patients with severe symptomatic aortic valve stenosis or symptomatic valvular disease due to failing of a surgical bioprosthetic aortic valve (approval number 30700BZX00072000). This application is submitted to add an indication for the treatment of patients with symptomatic valvular disease due to failing of a transcatheter bioprosthetic aortic valve, similar to the "Evolut PRO+ System" (approval number 30200BZX00272000) already approved.

(2) Non-clinical data

The following nonclinical data were submitted (data items were based on applicant submission data).

- Physical and chemical properties: frame radial strength test, finite element analysis, migration resistance.
- Stability and durability: mechanical failure mode test.
- Performance: hydrodynamic test.
- Usability engineering process: data on conformity to IEC 62366-1.

(3) Clinical data

The applicant submitted data for the U.S. TVT registry. The outline of the submitted data is as follows (reference to the clinical data section of the package insert, and table numbers, etc., are provided as necessary).

U.S. registry (TVT registry)

This is a retrospective analysis of patients who underwent transcatheter aortic valve in transcatheter aortic valve (hereinafter referred to as "TAV in TAV") using "Core Valve Evolut R" (approval number 22800BZX00414000), "Core Valve Evolut PRO" (approval number 23000BZX00196000), and "Evolut PRO+ System" (approval number 30200BZX00272000, PRO+ model, and FX model).

Table 1 Clinical results at 1 year postoperative Attempted population (TAV in TAV)

	N = 579	
	Kaplan-Meier Rate (Number of subjects, number of events)	
	30 days	1 year
All-cause mortality	3.4% (19, 19)	15.3% (75, 75)
Cardiovascular mortality	2.3% (13, 13)	5.3% (26, 26)
Any stroke	3.7% (21, 22)	4.5% (25, 26)
Ischemic stroke	3.5% (20, 20)	4.3% (24, 24)
Hemorrhagic stroke	0.4% (2, 2)	0.4% (2, 2)
Undetermined stroke	0.0% (0, 0)	0.0% (0, 0)
Transient ischemic attack (TIA)	0.0% (0, 0)	0.7% (3, 3)
Major vascular complication	1.6% (9, 9)	1.8% (10, 10)
Life threatening/major bleeding	7.9% (45, 46)	9.7% (53, 57)
Myocardial infarction	0.4% (2, 2)	1.7% (8, 8)
New requirement for dialysis	1.6% (9, 9)	2.0% (11, 11)
Conduction/native pacer disturbance req pacer/ICD[1)]	5.1% (29, 29)	6.2% (34, 35)
Conduction/native pacer disturbance req pacer/ICD[2)]	6.8% (28, 28)	8.0% (32, 33)
Aortic valve re-intervention	0.9% (5, 5)	0.9% (5, 5)
Unplanned other cardiac surgery or intervention	1.8% (10, 10)	2.2% (12, 12)
Unplanned vascular surgery or intervention	5.6% (32, 35)	5.8% (33, 37)
Device thrombosis	0.2% (1, 1)	0.2% (1, 1)
Valve-related readmission	0.4% (2, 2)	1.4% (7, 7)

[1)] Subjects with pacemaker or ICD at baseline are included.

[2)] Subjects with pacemaker or ICD at baseline are not included.

Table 2 Mean pressure gradient and aortic valve area Implanted population

	23 mm N = 140	26 mm N = 253	29 mm N = 139	34 mm N = 42
Mean gradient across aortic valve (mmHg)				
Baseline	44.9 ± 17.0 (130)	41.0 ± 15.4 (229)	41.3 ± 19.0 (95)	37.9 ± 17.8 (23)
Post-procedure	16.0 ± 8.4 (127)	12.5 ± 6.7 (230)	10.7 ± 6.6 (123)	10.5 ± 6.0 (38)
30 days	15.0 ± 7.2 (106)	11.2 ± 5.7 (182)	10.5 ± 5.8 (93)	9.3 ± 4.6 (38)
1 year	14.0 ± 7.2 (66)	10.9 ± 6.0 (113)	10.0 ± 4.8 (51)	10.0 ± 4.1 (21)
Aortic valve area (cm^2)				
Baseline	0.7 ± 0.3 (115)	0.8 ± 0.3 (208)	0.9 ± 0.4 (92)	0.9 ± 0.6 (22)
Post-procedure	1.4 ± 0.5 (103)	1.6 ± 0.5 (183)	1.9 ± 0.8 (100)	2.1 ± 0.8 (33)
30 days	1.5 ± 0.5 (40)	1.5 ± 0.6 (56)	2.1 ± 0.8 (23)	2.0 ± 0.7 (6)
1 year	1.5 ± 0.6 (31)	1.9 ± 0.6 (41)	1.9 ± 0.7 (22)	1.6 ± 0.5 (5)

Table 3 Total aortic and paravalvular regurgitation Implanted population (N = 575)

	Baseline	Post-procedure	30 days	1 year
Total aortic regurgitation grade				
None	14.9% (85/572)	58.2% (308/529)	55.6% (235/423)	59.2% (151/255)
Trace/Trivial	10.7% (61/572)	22.7% (120/529)	21.3% (90/423)	17.6% (45/255)
Mild	22.6% (129/572)	18.0% (95/529)	19.1% (81/423)	19.6% (50/255)
Moderate	29.0% (166/572)	0.9% (5/529)	4.0% (17/423)	2.7% (7/255)
Severe	22.9% (131/572)	0.2% (1/529)	0.0% (0/423)	0.8% (2/255)
Paravalvular regurgitation grade				
None	NA	79.8% (383/480)	76.7% (299/390)	80.9% (182/225)
Mild	NA	19.0% (91/480)	20.5% (80/390)	15.1% (34/225)
Moderate	NA	0.8% (4/480)	2.8% (11/390)	3.1% (7/225)
Severe	NA	0.4% (2/480)	0.0% (0/390)	0.9% (2/225)

2. Review results

As a result of the review of the submitted data, PMDA concluded that the product could be approved for the following intended use shown below with the following approval conditions. Since the approval of the additional indication of this product is expected to shift from the current model of the "Evolut PRO+ System"

(approval number 30200BZX00272000) to the procedure using this product, it was considered appropriate to conduct an investigation including this product regarding the use-results survey designated at the time of approval of the "Evolut PRO+ System." Underlined parts of the intended use and approval conditions to be changed in this application for partial change are shown.

<Intended Use>

This product is a self-expanding transcatheter aortic valve and is intended for use in the following patients.

- Patients with severe symptomatic aortic valve stenosis attributed to degenerative calcification of the native aortic valve cusp of which treatment with this product is considered as their best therapeutic option. In the case of chronic dialysis patients, however, the treatment with this product is limited to patients who are not eligible for surgery and of which treatment with this product is considered as their best therapeutic option.
- Patients with symptomatic valvular disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve who are not eligible for surgery and of which treatment with this product is considered as their best therapeutic option. However, this product is not implanted in a surgically implanted bioprosthetic aortic valve in the size of 34 mm. Except for the patients who have multiple bioprosthetic valves in the aortic position.

<Conditions for Approval>

1. Transcatheter aortic valve replacement

(1) Treatment in all eligible patients

1） The applicant is required to take necessary measures in cooperation with related academic societies to ensure that this product is used by surgeons with adequate knowledge and experience in the treatment of symptomatic severe aortic valve stenosis at medical institutions with a well-established system for possible complications in association with the treatment with the product.

2） The applicant is required to take necessary measures in cooperation with related academic societies to ensure that this product is used, in compliance with the indication, by surgeons as described in 1) in the treatment using this product after acquiring sufficient skills for using this product and adequate knowledge about procedure-related complications by attending relevant training courses or by other means.

3） The applicant is required to take necessary measures in cooperation with related academic societies to ensure that this product is used only in intended patients for the treatment with the product.

(2) Treatment in patients not on chronic dialysis with severe symptomatic aortic valve stenosis attributed to degenerative calcification of the native aortic valve cusp who are eligible for surgery and of which treatment with this product is considered as their best therapeutic option

1） The applicant is required to submit reports on the results of analyses of long-term prognosis of patients in the clinical study included in this regulatory submission to PMDA and to take appropriate measures as necessary.

(3) Treatment in patients with symptomatic valvular disease due to failing (stenosed, insufficient, or combined) of a transcatheter bioprosthetic aortic valve who are not eligible for surgery and of which treatment with this product is considered as their best therapeutic option

1） The applicant is required to conduct a use-results survey covering all patients treated with this product, report the results of interannual analyses to the PMDA, and take other appropriate measures as necessary.