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 51
Term name	:	Atherectomy ablative angioplasty catheter
Brand name	:	Peripheral Orbital Atherectomy System
Applicant	:	Abbott Medical Japan LLC
Date of application	:	May 28, 2025
Date of approval	:	February 19, 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 atherectomy ablative angioplasty catheter that is percutaneously inserted into peripheral vessels and removes calcified lesions by rotating the catheter distal portion. Although the indication is substantially equivalent to the approved product by another manufacturer, the product differs mainly in the structure of the catheter distal portion. An expert discussion was held to obtain opinions on post-marketing safety measures.

(2) Non-clinical data

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

- Electrical safety and electromagnetic compatibility: Materials demonstrating conformity with IEC 60601-1:2005/A2 2010 and IEC 60601-1-2:2014.
- Biological safety: (Peripheral Orbital Atherectomy Device (P-OAD)) cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-derived pyrogen, hemocompatibility; (Guidewire) cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-derived pyrogen, and hemocompatibility. Other tests were omitted based on evaluation.
- Mechanical safety: Particle generation test by abrasion, orbital test.
- Stability and durability: Omitted based on "Handling of Stability Studies Related to the Determination of the Shelf Life in the Application for Marketing Approval (Certification) of Medical Devices" (PFSB/ELD/OMDE Notification No. 1227-5, dated December 27, 2012).
- Performance: Rotational speed test, kink resistance test, etc.
- Usability: Materials demonstrating conformity with the usability engineering process IEC 62366-1:2015 / AMD1: 2020.

(3) Clinical data

The applicant submitted the results of a domestic clinical trial (KAIZEN study; hereinafter referred to as "the clinical trial"). 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 clinical trial was a prospective, multicenter clinical trial conducted in Japan to evaluate the effectiveness and safety of the product in subjects with calcified lesions of the superficial femoral artery (Superficial Femoral Artery: SFA) and popliteal artery (Popliteal artery: POP) that were expected to be undilatable with standard balloon angioplasty (Plain Old Balloon Angioplasty: POBA), under the clinical environment in Japan. The analysis cohort for evaluation of effectiveness and safety included 67 subjects, and treatment with OAD was performed in all subjects (Intent-to-Treat: ITT population). Of these, 66

subjects judged appropriate by independent eligibility assessment physicians were included in the primary endpoint main analysis (Modified ITT: mITT population). The locations of target lesions were as shown in the table below.

Target lesion	Roll-in (n=14)	FAS/ITT (n=67)	mITT (n=66)
Proximal SFA	2/14 (14.3%)	16/67 (23.9%)	16/66 (24.2%)
Mid SFA	7/14 (50.0%)	24/67 (35.8%)	23/66 (34.8%)
Distal SFA	6/14 (42.9%)	33/67 (49.3%)	32/66 (48.5%)
POP1	2/14 (14.3%)	19/67 (28.4%)	19/66 (28.8%)
POP2	2/14 (14.3%)	16/67 (23.9%)	16/66 (24.2%)

As a result of the clinical trial, the acute device success rate, which was the primary endpoint, was 83.3% (55/66).

Endpoint result	Roll-in (n=14)	FAS/ITT (n=67)	mITT (n=66)
Primary endpoint (acute device success)	11/14 (78.6%)	56/67 (83.6%)	55/66 (83.3%)
Residual stenosis rate ≤50% after concomitant use with POBA after OAD	13/14 (92.9%)	67/67 (100%)	66/66 (100%)
No complications attributable to OAS	12/14 (85.7%)	56/67 (83.6%)	55/66 (83.3%)

In the clinical trial, distal embolization was observed in 10 cases. Analyses were conducted comparing cases with and without postoperative distal embolization (DE) regarding total calcification length within the target lesion, mean number of OAD passes, mean OAD ablation time and crown size.

	DE cases	Non-DE cases
Mean calcification length (mm) Site report	89.5 ± 54.39	57.4 ± 37.30
Mean calcification length (mm) Core lab assessment	102.5 ± 49.56	62.8 ± 41.99
Mean number of OAD passes	12.7 ± 3.09	11.0 ± 5.43
Mean OAD ablation time	359.6 ± 93.04	320.4 ± 140.79
Crown size 1.25 mm	0.0% (0/10)	7.0% (4/57)
1.50 mm	40.0% (4/10)	66.7% (38/57)
2.00 mm	60.0% (6/10)	29.8% (17/57)

In addition, the relationship between ablation time for each case and DE incidence was analyzed using quartiles (Q1–Q4). The shortest total operating time among DE cases was 235 seconds.

	Total operating time (sec)	DE incidence rate (n)
Q1	40.0 – 237.5	5.9% (1/17)
Q2	237.5 – 308.0	23.5% (4/17)
Q3	308.0 – 416.0	6.2% (1/16)
Q4	416.0 – 717.0	23.5% (4/17)

A comparison between the overseas registry (CONFIRM registry)[1] and the clinical trial in terms of mean OAS ablation time and DE incidence rate is as shown below.

	The clinical trial	CONFIRM registry (ATK/POP)
Mean OAS operating time (sec)	326.3 ± 134.90	120.4
DE incidence rate	15.2%	3.0%

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the product could be approved with the following approval conditions.

<Intended use>

Peripheral Orbital Atherectomy System is intended to be used in lesions (excluding in-stent lesions) in the superficial femoral artery and/or proximal popliteal artery with severe calcification, where a balloon catheter for percutaneous transluminal angioplasty used for predilation prior to drug-coated balloon treatment is unable to pass or is difficult to dilate, for the purpose of facilitating predilation by removing rigid atheromatous plaques and stenotic lesions.

<Conditions for Approval>

1. The applicant is required to take necessary measures to ensure that physicians with sufficient knowledge and experience in endovascular treatment for peripheral arterial occlusive disease, as well as adequate operational skills with the product and knowledge of procedure-related adverse events, at medical institutions with an established system for the treatment.
2. The applicant is required to take necessary measures, including dissemination of the guideline for proper use developed in cooperation with relevant academic societies, offering training programs, etc.

[1] Das, T., et al., Technique optimization of orbital atherectomy in calcifiedperipheral lesions of the lower extremities: the CONFIRM series, a prospective multicenter registry. Catheter Cardiovasc Interv, 2014. 83(1): p. 115-22