

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 central circulatory embolectomy
Brand name	:	Rotarex Endovascular System
Applicant	:	Medicon Co., Ltd.
Date of application	:	October 29, 2025
Date of approval	:	July 21, 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 central circulatory embolectomy used to percutaneously fragment and remove thrombus and restore blood flow in atherothrombotic lesions excluding chronic occlusive lesions in the femoropopliteal artery intended for patients requiring prompt treatment for whom surgical thrombectomy and existing percutaneous thrombectomy are difficult to perform or are expected to provide no effective therapeutic benefit. This product differs from another manufacturer's approved device in that it mechanically fragments thrombus through rotation of the catheter tip. An expert discussion was held to obtain opinions on the appropriateness of the clinical evaluation and post-marketing risk management.

(2) Non-clinical data

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

- Physicochemical properties: (Catheter) surface characteristics, durability, etc.; (Guidewire) surface characteristics, tensile strength, etc.
- Electrical safety and electromagnetic compatibility: data demonstrating conformity with IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014/AMD1:2020
- Biological safety: (Catheter and Guidewire) cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity, and hemocompatibility
- Performance: thrombus aspiration performance test, animal test
- Software life cycle: data demonstrating conformity with IEC 62304:2006/AMD1:2015
- Usability: data demonstrating conformity with IEC 60601-1-6:2010/AMD2:2020

(3) Clinical data

The applicant submitted the clinical evaluation report consisting of the results of a post-market clinical follow-up study (PMCF study) conducted in Europe, the results of a literature review, and other data. As the main results, the outline of the PMCF study is as follows (with reference to the "Clinical Results" section of the package insert and adjusted as appropriate).

A prospective, multicenter, non-randomized, multiple-cohort observational study was conducted at 14 European centers in 220 patients with lesions in native arteries, stents, stent grafts, bypass grafts, or native vascular shunts outside the cardiopulmonary, coronary, and cerebral circulations. Of these patients, 135 had guidewire-crossable atherothrombotic lesions in the lower extremity arteries and were included in the clinical evaluation analysis population. In the 135 patients, as the efficacy endpoint, technical success (residual stenosis is no greater than 50% directly after use of the product), was 50.75% (68/134), and procedural success (residual stenosis is no greater than 30% after adjunctive endovascular treatment when such treatment was

performed following use of the product) was 97.01% (130/134). With respect to safety evaluation during the 24-month follow-up period, all-cause mortality was 6.67% (9/135), and none of the deaths was related to the device or procedure. No unplanned major amputation of the target limb was reported. Clinically driven target lesion revascularization (CD-TLR) was 31.11% (42/135). Procedure- or device-related bleeding-related adverse events included perforation in 0.74% (1/135), arterial dissection in 2.22% (3/135), other bleeding-related adverse events in 8.89% (12/135), and distal embolization in 8.89% (12/135), all of which resolved without requiring additional surgical intervention, either without treatment or following medical or endovascular treatment.

Table. Breakdown of the clinical evaluation analysis population

Breakdown	N (135)
Vessel type	
Native vessel occlusion	59
Stent or stent-graft occlusion	67
Bypass graft occlusion	9
Presentation	
Acute (within 24 hours after symptom onset)	23
Subacute (>24 hours to 4 weeks after symptom onset)	112

Table. Breakdown of adjunctive endovascular treatment in the clinical evaluation analysis population

Breakdown	N (135)
No additional treatment	3
Additional treatment	132
With stent treatment	69
Without stent treatment	63
• Balloon*	57
• Thrombolysis*	14
• Other: aspiration catheter*	1

* Multiple selections were allowed.

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the efficacy and safety of the product could be largely explained in non-clinical studies. Considering that some clinical use experience is shown in the clinical evaluation report, PMDA concluded that the product could be approved with the following conditions of approval. This product is designated as a medical device subject to a use-results survey and the use-results survey period should be 4 years.

<Intended use>

This product is used to percutaneously fragment and remove thrombus and restore blood flow in atherothrombotic lesions excluding chronic occlusive lesions in the femoropopliteal artery intended for

patients requiring prompt treatment for whom surgical thrombectomy and existing percutaneous thrombectomy are difficult to perform or are expected to provide no effective therapeutic benefit.

<Conditions of approval>

1. The applicant is required to take necessary measures to ensure that patients are selected appropriately by physicians who have sufficient knowledge and experience in the treatment of the indicated disease and have acquired sufficient skills to operate the product and adequate knowledge of procedure-related complications at medical institutions with an established system for the treatment, including dissemination of the guideline for proper use developed in collaboration with relevant academic societies, offering training programs, etc.
2. The applicant is required to conduct a post-marketing survey covering all patients treated with the product until data from a specific number of patients have been accumulated, to submit annual reports to the Pharmaceuticals and Medical Devices Agency, and to take appropriate measures as necessary.