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 51
Term name	:	Central circulatory intravascular embolization prosthesis
Brand name	:	Surpass Evolve Flow Diverter System
Applicant	:	Stryker Japan K.K.
Date of application	:	October 27, 2025
Date of approval	:	April 3, 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 flow diverter system used for the endovascular treatment of intracranial aneurysms located in the internal carotid artery from the petrous segment to the supraclinoid segment that are difficult to treat by surgical procedures or coil embolization, excluding the acute rupture phase.

The purpose of this application is to change the maximum aneurysm diameter of the indicated aneurysms from 10 mm or greater to 5 mm or greater.

(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 a clinical evaluation report consisting of overseas literature, mainly based on the SEASE study conducted in North America and Europe. The outline of the submitted data is as follows (with reference to the "Clinical Results" section of the package insert and adjusted as appropriate).

A single-arm, retrospective, observational, multicenter cohort study (SEASE study) using this product was conducted in patients with unruptured wide-neck intracranial aneurysms. In 15 institutions in North America and Europe, a total of 305 patients with 332 aneurysms were evaluated for the effectiveness and safety of this product. In this study, the primary effectiveness endpoint, "complete occlusion rate (Raymond-Roy Class 1) at the final follow-up," was 73.0% (233/319 aneurysms). The incidence of the primary safety endpoint, "major stroke (ischemic/hemorrhagic) in the target vessel territory or procedure-related death," was 2.1% (6 cases). Procedure-related death was observed in 0.7% (2 cases).

In addition, a sub-analysis was conducted in 129 patients with 135 aneurysms classified as small and medium-sized (maximum aneurysm diameter $\leq$ 12 mm) within this study. In this sub-analysis, the primary effectiveness endpoint, "complete occlusion rate (Raymond-Roy Class 1) at the final follow-up," was 77.1% (101/131 aneurysms). The incidence of the primary safety endpoint, "major stroke (ischemic/hemorrhagic) in the target vessel territory or procedure-related death," was 1.6% (2 cases). Procedure-related death was observed in 0.8% (1 case).

2. Review Results

PMDA concluded that the clinical efficacy caused by the intended physical effect of the product is considered to be publicly known in medical and pharmaceutical fields, and that 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 partial change could be approved.

<Intended use> *Changes are indicated by underlining.

This product is used for the endovascular treatment of intracranial aneurysms located in the internal carotid artery from the petrous segment to the supraclinoid segment that are difficult to treat by surgical procedures or coil embolization, with a maximum aneurysm diameter of 5 mm or greater and a wide neck (neck length of 4 mm or greater or dome-to-neck ratio of less than 2), excluding the acute rupture phase.