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	:	Bronchial balloon catheter
Brand name	:	Bronchial hemostatic balloon
Applicant	:	Fuji Systems Corporation
Date of application	:	August 29, 2025
Date of approval	:	April 20, 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 bronchial balloon catheter and tracheal tube used in a balloon occlusion method for hemostasis after transbronchial cryobiopsy. It is also inserted orally into the trachea for purposes such as securing the airway, administering inhalation anesthetics and medical gases, providing ventilation, etc.

The product was developed as a device specialized for bronchial hemostasis after cryobiopsy by referring to an already approved product of another company, “Fogarty Catheter” (Approval No. 15100BZY00938000), and an already certified product, “Portex Tracheal Tube” (Certification No. 221AIBZX00019000).

(2) Non-clinical data

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

- Biological safety: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity
- 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: Physical tests for tracheal tubes, physical tests for balloon catheters, equivalence tests
- Method of use: Tests related to the expansion diameter of the occlusion balloon
- Usability: Materials demonstrating conformity with the usability engineering process JIS T 62366-1:2022

(3) Clinical data

The applicant submitted the clinical evaluation report consisting of the literature in Japan and overseas. The outline of the submitted data is as follows (with reference to the “Clinical Results” section of the package insert and adjusted as appropriate).

1) Evaluation of efficacy

In three publications used for the evaluation, balloon tamponade using a balloon catheter was performed in a total of 22 cases. For mild bleeding, hemostasis was achieved with balloon tamponade alone in 6 cases (27.3%). For moderate to severe bleeding, hemostasis was achieved in 15 cases (68.2%) by combining balloon tamponade with other measures such as the application of hemostatic agents.

2) Evaluation of safety

In six publications used for the evaluation, balloon tamponade using a balloon catheter was performed in a total of 522 cases. Adverse events considered to be directly attributable to the balloon catheter included balloon displacement in 28 cases (5.4%) and balloon burst in 4 cases (0.8%).

2. Review Results

PMDA concluded 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 product could be approved.

<Intended use>

This product is a balloon catheter used in a balloon occlusion method for hemostasis after transbronchial cryobiopsy.

In addition, it is inserted orally into the trachea for purposes such as securing the airway, administering inhalation anesthetics and medical gases, providing ventilation, etc.