Review Summary

March 9, 2026

Pharmaceuticals and Medical Devices Agency

The following are 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	:	Pacemaker/defibrillator lead removal kit
Brand name	:	TightRail family
Applicant	:	Philips Japan Corporation
Date of application	:	April 17, 2025
Date of approval	:	December 3, 2025
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 a pacemaker/defibrillator lead removal kit for easy removal of cardiac leads. The purpose of development of the product is to expand the option of devices for percutaneous lead removal in Japan. Compared with other manufacturers' approved products, the main difference is that the product has a mechanism to expose and rotate the blade from the tip of the sheath by operating the handle. However, the intended use and the method of use are substantially equivalent, and there is no particular novelty.

(2) Non-clinical data

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

- Biological safety: cytotoxicity, sensitization, intradermal reaction, acute systemic toxicity, pyrogenicity and hemocompatibility.
- Stability: 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: axial load tests, comparative tests against similar medical devices, etc.
- Directions for use: data on conformity to usability engineering process IEC 62366-1:2015 + AMD1:2020.

(3) Clinical data

The applicant submitted a clinical evaluation report centered on literature comparing the efficacy and safety of the product and similar products in Europe.[1,2]

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>

The TightRail family is used percutaneously for the purpose of dilating adhesive tissue to facilitate the removal of cardiac leads.

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[1] Cay S, et al, Comparison of two types of rotational mechanical dilatator sheath: Evolution® and TightRail™, Pacing Clin Electrophysiol 2019,42(9):1226–1235.

[2] Bahadır N, et al, Comparison of acute and long-term outcomes of Evolution® and TightRail™ mechanical dilator sheaths during transvenous lead extraction, J Cardiovasc Electrophysiol 2021;32:1395-1404.