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 7, Organ Function Replacement Device
Term name	:	Implantable endocardial pacemaker electrode/lead
Brand name	:	INGEVITY AFx
Applicant	:	Boston Scientific Japan Corporation
Date of application	:	October 27, 2025
Date of approval	:	May 15, 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 a pacemaker lead used in conjunction with implantable cardiac pacemakers and other implantable cardiac devices, and is conditionally compatible with magnetic resonance imaging (MRI) examinations only when the imaging conditions are met. This application is a partial change application of marketing approval that seeks to make the product available for use in left bundle branch area pacing (LBBAP).

(2) Non-clinical data

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

- Performance: fatigue tests, simulated use tests, etc.
- Directions for use: tests on safety during MRI examinations.
- Usability engineering process: 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 the results of the INSIGHT-LBBA study, an investigator-initiated observational study conducted in the United States.[1]

2. Review Results

PMDA concluded that the application based on the clinical evaluation report is acceptable because the clinical efficacy caused by the intended physical effect of the product is considered to be publicly known in medical and pharmaceutical fields. As a result of the review of the submitted clinical evaluation report, PMDA concluded that the product could be approved.

[1] Friedman DJ, Shadrin I, Goldbarg S, et al. Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA. Heart Rhythm. 2025 Aug;22（8）:2047-2054.