

Review Summary

May 19, 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 : Medical products 4, Orthopedic products

Term name : Spinal cage

Brand name : Transcend PEEK LIF cage/AMP plate

Applicant : Alphatec Spine, Inc.

Date of application : June 9, 2025

Date of approval : February 25, 2026

Application : New medical device Improved medical device (with clinical
classification data)
Improved medical device (without clinical data)

New approval / partial : New Approval Partial Change
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 : Designated as medical devices with high medical need
special mention 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 purpose of this application is to allow lateral interbody fusion to be performed on patients in the prone position (hereinafter referred to as "prone LIF") when using the lumbar, while lateral interbody fusion (hereinafter referred to as "lateral LIF") has been performed on patients in the lateral position. The product itself is unchanged.

(2) Non-clinical Data

The following nonclinical data were submitted (data items were based on applicant submission data).

- Conformance to usability matters

(3) Clinical data

The applicant submitted a clinical evaluation report that focused on the overseas literature. The outline of the clinical evaluation report is as follows (the clinical results section of the package insert is cited).

The efficacy and safety of prone LIF in the lumbar spine were evaluated in clinical studies. The prone position LIF in this clinical evaluation is limited to patients who use Alphatec's dedicated patient positioner and dedicated access surgical instruments. Cases in the existing lateral position LIF were selected as controls.

A literature search was performed for prone and lateral LIF, and the following efficacy and safety measures were tested for non-inferiority in the two groups.

Efficacy measures: operating time per vertebral body, blood loss per vertebral body, change in regional lordosis, change in lumbar lordosis

Safety measures: long-term neurological deficits, macrovascular injury, and visceral injury

The non-inferiority test confirmed the non-inferiority of prone LIF to lateral LIF except for changes in lumbar lordosis.

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 partial change could be approved.

<intended use > * Indicates the changed part with an underline.

The Transcend PEEK LIF cage/AMP plate is used in patients who require lateral fixation because of spinal disease, instability, etc. The cage is used to replace the intervertebral disc or part of the spinal cord to replace, correct, or repair the height of the spinal column structure, and is used in one vertebra. The intervertebral level to be applied varies depending on the patient's position in the surgical procedure.

For lateral position: thoracic and lumbar (T3-T4 to L4-L5)

For prone position: lumbar (L1-L2 to L4-L5)

AMP Plate and Screw are used to fix, support or align the spine and are used in the lumbar (L1-L2 to L4-L5) in conjunction with the cage.