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	:	Absorbable bone regeneration material
Brand name	:	Verte
Applicant	:	Menicon Co., Ltd.
Date of application	:	Jun. 6, 2025
Date of approval	:	Feb. 13, 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 an absorbable bone regeneration material that assists bone regeneration by mixing with autologous bone and implanting in bone defects. A similar approved product is a granular or block-shaped product with β-tricalcium phosphate (β-TCP) as the main ingredient, while the product is a gel-shaped product with a peptide as the main ingredient. It was developed based on the concepts that autologous bone can be uniformly mixed and autologous bone can be stably retained in the implantation site. Although there is a difference between the product and approved product in the main ingredient, it is substantially equivalent in that it is used in combination with autologous bone to aid in the regeneration of bone tissue, and there is no particular novelty.

(2) Non-clinical data

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

- Physical and chemical properties: description, pH, etc.
- Biological safety: cytotoxicity, sensitization, intracutaneous reactivity, pyrogenicity, acute systemic toxicity, subacute systemic toxicity, subchronic/chronic systemic toxicity by intramuscular implantation, implantation, genotoxicity, hemolysis
- Stability: Test results using samples after 36.3 months (description, pH, sterility, etc.)
- Performance: Rabbit and dog bone implantation studies
- Pharmacokinetics: Pharmacokinetics in rat bone implant, pharmacokinetics in rabbits by intraperitoneal/intravenous administration, in vitro degradability test, cytotoxicity test of metabolites
- Usability: Documents related to compliance with JIS T 62366-1:2022

(3) **Clinical data**

The applicant submitted a domestic clinical study using the self-assembling peptide gel CK2-092 as a bone replacement at the time of posterior lumbar vertebral interbody fusion. The outline of the study is as follows (reference to the clinical results section of the package insert).

An open-label, single-arm, multicenter study was conducted at three sites in Japan to evaluate the efficacy and safety of the product in patients requiring posterior lumbar vertebral interbody fusion for autologous bone transplantation using historical data as a control.

(1) Effectiveness

The bone union rate at the autologous bone graft site 12 months after surgery was 95.12% as a result of the evaluation of radiographic images by the imaging evaluation committee. Compared with the bone union rate (65%) in the treatment of a combination of β-TCP and autologous bone graft, which is historical data, the efficacy of the product was demonstrated.

(2) Adverse events

Moderate adverse events for which a causal relationship with the product could not be ruled out occurred in 1 subject each. There were no serious adverse events for which a causal relationship with the product could not be ruled out.

・Infection

・Poor wound healing

2. Review results

As a result of the review of the submitted data, PMDA concluded that the product could be approved for the following intended use shown below.

< Intended use>

The Verte assists in bone regeneration by mixing with autologous bone and implanting in bone defects. The product is used for applications where direct load is not applied to the product itself or for applications where initial fixation of the implant is not involved.