

Review Summary

September 15, 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 Product 72 lens for vision correction
Term name	:	Single-use colored vision corrective contact lens
Brand name	:	1day SD01H-SUV
Applicant	:	SEED Co., Ltd.
Date of application	:	October 24, 2025
Date of approval	:	July 21, 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 single-use colored vision corrective contact lens for daily wear consisting of a silicone hydrogel with a water content of 53% and an oxygen permeability (Dk) of 114×10^{-11} (cm²/sec)·(mLO₂/(mL × mmHg)). It was developed as a new material to improve the oxygen permeability compared to that of the approved product “1day SD01H-S” (Approval No. 30300BZX00275000).

(2) Non-clinical data

The following non-clinical data were submitted based on Appendix 2, "Technical Standards for Soft (Hydrogel) Contact Lenses," of the "Revision of the Approval Standards for Contact Lenses (Part 2)" (PSEHB Notification No. 0411-8 dated April 11, 2019) (hereinafter referred to as "Approval Standards") (data items were based on the data submitted by the applicant).

- Physical and Chemical properties: Luminous transmittance test, Oxygen permeability test, etc.
- Biological safety: Cytotoxicity test, Skin sensitization test, Rabbit ocular wear test, Bacterial reverse mutation test and Chromosomal aberration test
- Stability and Durability: Long-term Stability Test
- Performance: Approval Standards conformity testing, bifocal contact lens testing, and progressive power contact lens testing
- Usability: data indicating conformity with JIS T 62366-1:2022

(3) Clinical data

The applicant submitted the results of a domestic clinical study. The outline of the study is as follows

(the clinical results section of the package insert is cited).

From July 2024 to February 2025, a 13-week clinical study was conducted at 4 sites in Japan in 63 subjects (126 eyes) with bilateral refractive errors (39.1 ± 8.6 years of age) to evaluate the device for daily wear and daily replacement. The analysis population comprised 63 subjects (126 eyes). Adverse events for which a causal relationship to the device could not be ruled out included corneal disorder (1.6%), superficial punctate keratitis (0.4%), dry eye (0.4%), corneal deposits (0.2%), and corneal erosion (0.2%). All adverse events were mild, and no temporary discontinuation of lens wear was required. The proportion of eyes with a lens-corrected visual acuity of 1.0 or better was 100.0%, indicating that the device was effective for visual correction.

2. Review results

As a result of the review of the submitted data, PMDA concluded that the product could be approved.

< Intended use >

Visual acuity correction