

Review Summary

May 19, 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 : Medical Product 72 lens for vision correction
Term name : Heparin-coated posterior chamber lens
Brand name : CTLUCIA 621PY
Applicant : Carl Zeiss Meditech Co., Ltd.
Date of application : April 28, 2025
Date of approval : January 20, 2026
Application classification : New medical device Improved medical device (with clinical 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 special : Designated as medical devices with high medical need
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

CT LUCIA 621PY is a posterior chamber lens with an inserter, consisting of a heparin-coated monofocal intraocular lens loaded into an inserter for correcting vision in aphakia eyes. The shape is the same as the approved product "CT LUCIA 621P " (Approval No. 30700BZX00305000, Carl Zeiss Meditech Co., Ltd.), and yellow dye is added intended to absorb blue light.

(2) Non-clinical Data

The following nonclinical data were submitted based on "Revision of the Approval Standards for Intraocular Lenses" (PSEHB Notification No. 1002-1, dated October 2, 2017) (data items are based on data submitted by the applicant).

- Physical and Chemical Properties: Leachables Test, Hydrolysis Stability Test, Nd-YAG Exposure Test
- Biological Safety: (IOL) Cytotoxicity, Genotoxicity, Sensitization, Ocular Implantation, Eye Irritation, (Injector) Cytotoxicity, Sensitization, Eye Irritation
- Stability and Durability: Product Stability Test, Transport Stability Test
- Performance: Appearance test, Dimension test, Optical property test, Mechanical property test, Return to shape after folding evaluation test
- Method of use: Documents related to conformance to JIS T 62366-1:2022 usability engineering process

(3) Clinical data

The results of a multicenter single-group study using similar product that differed in some materials additives, and shape from this product have been submitted. The outline of this study is as follows (the clinical results section of the package insert is cited and maintained as necessary).

A prospective, multicenter, open-label clinical study in adult subjects requiring cataract surgery with intraocular lens implantation was conducted at 15 sites in the United States. A total of 339 subjects received CTLUCIA 611P (monofocal intraocular lens, which differs in ingredients and shape from this product) in one eye and were followed for 12 months after surgery. Best corrected distance visual acuity (BCDVA), uncorrected distance visual acuity (UCDVA), and manifest refraction spherical equivalent (MRSE) were assessed as efficacy endpoints, and adverse events (AE) were assessed as safety endpoints. At 12 months postoperatively, 99.4% (308 of 310) of eyes achieved BCDVA of 0.3 log MAR or better, achieving the International Organization for Standardization (ISO 11979-7:2006) safety and performance endpoint (SPE) ($p < 0.0001$). At 12 months postoperatively, 92.9% (288 of 310) of eyes had UCDVA of 0.3 log MAR or better. The postoperative MRSE (mean \pm SD) at 12 months was $-0.0270 \pm 0.44966D$. Photologic AEs related to the investigational device were reported in 3 patients (0.9%, 3 of 339 patients).

2. Review Results

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

<Intended use >

Sight correction of an aphakic eye