

K252409 TearCare MGX System

Apr 27, 2026
269 days to decision

K252409 · Product code: **ORZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k252409/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Aug 1, 2025
Decision date	Apr 27, 2026
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sight Sciences, Inc.
Location	Laguna Beach, CA, US
Contact	Rachel Franco
510(k) history	11 submissions · 11 cleared · 2013-2026

CLINICAL EVIDENCE - NCT04795752

Safety And Effectiveness Of The TearCare® System In The Treatment Of The Signs And Symptoms Of Dry Eye Disease (SAHARA)

Status	Completed
Enrollment	345 patients (actual)
Study sites	14 sites
Condition studied	Dry Eye; Meibomian Gland Dysfunction
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Sep 23, 2024
Sponsor	Sight Sciences, Inc. (Industry)

Primary outcome

Tear Break-Up Time

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04795752