

K213045 TearCare SystemDec 21, 2021
90 days to decisionK213045 · Product code: **ORZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k213045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Sep 22, 2021
Decision date	Dec 21, 2021
Days to decision	90 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	Edward J. Sinclair
Website	https://www.sightsciences.com/us/
510(k) history	11 submissions · 11 cleared · 2013-2026

Sight Sciences, Inc. develops ophthalmic surgical devices, with a manufacturing facility in Laguna Beach, US. The company specializes in innovative solutions for eye surgery and tear film management. The company has received FDA 510(k) clearances from total submissions since 2013. All submissions focus on ophthalmic devices. The latest clearance was granted in 2026, confirming active regulatory engagement and ongoing product development. Sight Sciences's cleared portfolio includes surgical systems and viscosurgical products designed for anterior segment procedures. Notable...

CLINICAL EVIDENCE - NCT03588624**Study of the TearCare System in Dry Eye Disease**

Status	Completed
Enrollment	29 patients (actual)
Study sites	3 sites
Condition studied	Dry Eye
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 8, 2018
Sponsor	Sight Sciences, Inc. (Industry)

Primary outcome

Mean Change in Tear Break-Up Time (TBUT) at 1-month From Baseline

Secondary outcome

Mean Change in Ocular Surface Disease Index (OSDI) Score From Baseline to Month 1

Source: [ClinicalTrials.gov](https://clinicaltrials.gov/) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03588624