

**K231084 TearCare MGX System**Dec 27, 2023  
254 days to decisionK231084 · Product code: **ORZ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k231084/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Apr 17, 2023
Decision date	Dec 27, 2023
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sight Sciences, Inc.</b>
Location	Laguna Beach, CA, US
Contact	Rachel M. Franco
Website	<a href="https://www.sightsciences.com/us/">https://www.sightsciences.com/us/</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k231084/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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