

K232214 OMNI Surgical SystemAug 25, 2023
30 days to decisionK232214 · Product code: **MRH** · Ophthalmic
Source: <https://www.510kdatabase.net/k232214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Ophthalmic (MRH)
Date received	Jul 26, 2023
Decision date	Aug 25, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sight Sciences, Inc.
Location	Laguna Beach, CA, US
Contact	Ranjani Madhavan
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...
