

K202678 OMNI Surgical SystemMar 1, 2021
167 days to decisionK202678 · Product code: **MRH** · Ophthalmic
Source: <https://www.510kdatabase.net/k202678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Ophthalmic (MRH)
Date received	Sep 15, 2020
Decision date	Mar 1, 2021
Days to decision	167 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...