FDA 510(k) Premarket Notification

K201953 OMNI PLUS Surgical System

CLEARED

Aug 11, 2020
28 days to decision

K201953 · Product code: **MRH** · Ophthalmic
Source: https://www.510kdatabase.net/k201953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Ophthalmic (MRH)
Date received	Jul 14, 2020
Decision date	Aug 11, 2020
Days to decision	28 days
Third-party review	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' cleared portfolio includes surgical systems and viscosurgical products designed for anterior segment procedures. Notable...