FDA 510(k) Premarket Notification

K221188 ZEPTO Precision Capsulotomy System

CLEARED

Jun 23, 2022
59 days to decision

K221188 · Product code: **PUL** · Ophthalmic
Source: https://www.510kdatabase.net/k221188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Cutting, Radiofrequency, Electrosurgical, Ac-powered (PUL)
Date received	Apr 25, 2022
Decision date	Jun 23, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Centricity Vision, Inc.**
Location	Carlsbad, CA, US
Contact	Neal Hartman
510(k) history	3 submissions · 3 cleared · 2021-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221188/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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