FDA 510(k) Premarket Notification

K220030 Vista Ophthalmics Vitrectomy Probe

CLEARED

May 4, 2022
119 days to decision

K220030 · Product code: **MLZ** · Ophthalmic
Source: https://www.510kdatabase.net/k220030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vitrectomy, Instrument Cutter (MLZ)
Date received	Jan 5, 2022
Decision date	May 4, 2022
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vista Ophthalmics, LLC**
Location	Katy, TX, US
Contact	Don Knowles
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Pathways Group, Inc.**
Contact	Debe Deck

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov