FDA 510(k) Premarket Notification

K201724 Pentacam AXL Wave

CLEARED

Oct 21, 2020
120 days to decision

K201724 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k201724/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Jun 23, 2020
Decision date	Oct 21, 2020
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oculus Optikgerate GmbH**
Location	Woodinville, WA, US
Contact	Eckhard Loh
510(k) history	6 submissions · 6 cleared · 2003-2020

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Randy Prebula

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