FDA 510(k) Premarket Notification

K984443 ORBSCAN

CLEARED

Mar 5, 1999
81 days to decision

K984443 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k984443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Dec 14, 1998
Decision date	Mar 5, 1999
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Technolas Perfect Vision GmbH**
Location	Anaheim, CA, US
Contact	BETSY M JOHNSON
510(k) history	10 submissions · 10 cleared · 1999-2020