FDA 510(k) Premarket Notification

K964891 ORBSHOT KERATOMETER

CLEARED

Mar 26, 1997
110 days to decision

K964891 · Product code: **MMQ** · Ophthalmic
Source: https://www.510kdatabase.net/k964891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Topographer, Corneal, Ac-powered (MMQ)
Date received	Dec 6, 1996
Decision date	Mar 26, 1997
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orbtek, Inc.**
Location	Salt Lake City, UT, US
Contact	PIER CALACINO
510(k) history	2 submissions · 2 cleared · 1994-1997