FDA 510(k) Premarket Notification

K964751 CERALAS DIODE LASER SYSTEM (CERALAS D2)

CLEARED

Feb 21, 1997
87 days to decision

K964751 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k964751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Nov 26, 1996
Decision date	Feb 21, 1997
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ceram Optec, Inc.**
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	30 submissions · 30 cleared · 1992-2000