FDA 510(k) Premarket Notification

K960971 OCULIGHT GL

CLEARED

Aug 28, 1996
170 days to decision

K960971 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k960971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Mar 11, 1996
Decision date	Aug 28, 1996
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iriderm Div.**
Location	Mountain View, CA, US
Contact	THEODORE A BOUTACOFF
510(k) history	10 submissions · 10 cleared · 1989-1997