FDA 510(k) Premarket Notification

K080423 INTEGRE, MODEL LP581

CLEARED

Mar 11, 2008
25 days to decision

K080423 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k080423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Ophthalmic (HQF)
Date received	Feb 15, 2008
Decision date	Mar 11, 2008
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ellex Medical Pty, Ltd.**
Location	Adelaide, South Australia, AU
Contact	KEVIN HOWARD
510(k) history	13 submissions · 13 cleared · 1997-2022