

K081565 INTEGRE PRO, MODEL L2RYJul 2, 2008
28 days to decisionK081565 · Product code: **HQF** · Ophthalmic
Source: <https://www.510kdatabase.net/k081565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Ophthalmic (HQF)
Date received	Jun 4, 2008
Decision date	Jul 2, 2008
Days to decision	28 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026