

K190786 Eye PrimeApr 11, 2019
15 days to decisionK190786 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k190786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 27, 2019
Decision date	Apr 11, 2019
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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