

**K974522 3D I-SCAN**Feb 25, 1998  
85 days to decisionK974522 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k974522/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 2, 1997
Decision date	Feb 25, 1998
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ophthalmic Technologies, Inc.</b>
Location	Downsview, Ontario, CA
Contact	GEORGE MYERS
510(k) history	9 submissions · 8 cleared · 1995-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974522/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026