

**K070477 ORISON EMBRACE SYSTEM**Mar 9, 2007  
17 days to decisionK070477 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k070477/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 20, 2007
Decision date	Mar 9, 2007
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orison Corporation</b>
Location	Johnson City, TN, US
Contact	JOHN DIXON
510(k) history	2 submissions · 2 cleared · 2007-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070477/> 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 18, 2026