

**K101429 ECO SUPERGEL**Sep 15, 2010  
117 days to decisionK101429 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k101429/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 21, 2010
Decision date	Sep 15, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ceracarta Spa</b>
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101429/> 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 17, 2026