

**K102989 OPUS DIAGNOSTIC ULTRASOUND SYSTEM & TRANSDUCERS**Dec 9, 2010  
64 days to decisionK102989 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k102989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 6, 2010
Decision date	Dec 9, 2010
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chang Gung Medical Technology Co., Ltd. Linkou Fac</b>
Location	Dublin, CA, US
Contact	BOB LEIKER
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/k102989/> 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