

**K142982 OPUS 5100 Diagnostic Doppler Ultrasound System**Sep 3, 2015  
323 days to decisionK142982 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k142982/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 15, 2014
Decision date	Sep 3, 2015
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chang Gung Medical Technology Co., Ltd.</b>
Location	Taipei City, TW
Contact	CHENG MING CHEN
510(k) history	2 submissions · 2 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142982/> 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 16, 2026