

K133329 UGEO WS80A DIAGNOSTIC ULTRASOUND SYSTEMNov 27, 2013
29 days to decisionK133329 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k133329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 29, 2013
Decision date	Nov 27, 2013
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Samsung Medison Co., Ltd.
Location	Seoul, KR
Contact	PARK KYEONG-MI
Website	http://www.medison.com/
510(k) history	72 submissions · 72 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133329/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026