

K132228 UGEO PT60A DIAGNOSTIC ULTRASOUND SYSTEMAug 20, 2013
34 days to decisionK132228 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k132228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 17, 2013
Decision date	Aug 20, 2013
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132228/> 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