

**K032640 FULL FIELD BREAST IMAGING (FFBU) DIAGNOSTIC
ULTRASOUND SYSTEM**Sep 11, 2003
15 days to decisionK032640 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k032640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 27, 2003
Decision date	Sep 11, 2003
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	U-Systems, Inc.
Location	Los Altos,, CA, US
Contact	SHEILA W PICKERING
510(k) history	6 submissions · 6 cleared · 2001-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032640/> 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 18, 2026