K052355 AUTOMATED BREAST ULTRASOUND SYSTEM, MODEL ABUS

CLEARED

Sep 14, 2005
16 days to decision

K052355 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k052355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 29, 2005
Decision date	Sep 14, 2005
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**U-Systems, Inc.**
Location	Los Altos,, CA, US
Contact	ROBERT F LAWRENCE
510(k) history	6 submissions · 6 cleared · 2001-2005