FDA 510(k) Premarket Notification

K080930 MODIFICATION TO AUTOMATED BREAST ULTRASOUND SYSTEM, MODEL ABUS

CLEARED

Aug 7, 2008
127 days to decision

K080930 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k080930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 2, 2008
Decision date	Aug 7, 2008
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**U-System, Inc.**
Location	San Jose, CA, US
Contact	LISA SCOTT
510(k) history	1 submissions · 1 cleared · 2008-2008