FDA 510(k) Premarket Notification

K121422 APLIO 500/400/300 DIAGNOSTIC ULTRASOUND SYSTEM

CLEARED

Aug 16, 2012
94 days to decision

K121422 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k121422/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 14, 2012
Decision date	Aug 16, 2012
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Toshiba Medical Systems Coporation, Japan**
Location	Tustin, CA, US
Contact	CHARLEMAGNE CHUA
510(k) history	5 submissions · 5 cleared · 2011-2012