FDA 510(k) Premarket Notification

K070943 B-SCAN PLUS

CLEARED

Apr 19, 2007
15 days to decision

K070943 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k070943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 4, 2007
Decision date	Apr 19, 2007
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Accutome Ultrasound, Inc.**
Location	Malvern, PA, US
Contact	Jeffrey Wright
510(k) history	3 submissions · 3 cleared · 2004-2009