FDA 510(k) Premarket Notification

CLEARED

K121062 VIVID I DIAGNOSTIC ULTRASOUND SYSTEM, VIVID Q DIAGNOSTIC ULTRASOUND SYSTEM

Aug 17, 2012
133 days to decision

K121062 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k121062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 6, 2012
Decision date	Aug 17, 2012
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical System Israel , Ltd.**
Location	Wauwatosa, WI, US
Contact	BRYAN BEHN
510(k) history	4 submissions · 4 cleared · 2010-2012