FDA 510(k) Premarket Notification

K120882 SITE RITE PREVUE ULTRASOUND SYSTEM AND PINPOINT NEEDLE GUIDE

CLEARED

May 30, 2012
68 days to decision

K120882 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k120882/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 23, 2012
Decision date	May 30, 2012
Days to decision	68 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Bard Access Systems, Inc.**
Location	Salt Lake City, UT, US
Contact	HENRY BOLAND
510(k) history	21 submissions · 20 cleared · 1993-2025