FDA 510(k) Premarket Notification

CLEARED

K160792 Morpheus RealTime Ultrasound, Pathway RealTime Ultrasound, QuickScan Bladder Ultrasound

Apr 15, 2016
23 days to decision

K160792 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k160792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 23, 2016
Decision date	Apr 15, 2016
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Prometheus Group**
Location	Portsmouth, NH, US
Contact	Joshua Bird
510(k) history	11 submissions · 11 cleared · 1991-2016