FDA 510(k) Premarket Notification

K153620 Enovare Ultrasound System

CLEARED

May 5, 2016
139 days to decision

K153620 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k153620/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 18, 2015
Decision date	May 5, 2016
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oreon Technologies, Inc.**
Location	Harrytown, NY, US
Contact	Howard Fidel
510(k) history	1 submissions · 1 cleared · 2016-2016