

**K160343 SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable
Ultrasound Diagnostic Scanner**Apr 7, 2016
59 days to decisionK160343 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k160343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 8, 2016
Decision date	Apr 7, 2016
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beijing East Whale Imaging Technology Co., Ltd.
Location	Beijing, CN
Contact	JUNE LI
510(k) history	6 submissions · 6 cleared · 2013-2017

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