

K160942 SonablateDec 21, 2016
260 days to decisionK160942 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Apr 5, 2016
Decision date	Dec 21, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sonacare Medical, LLC
Location	Charlotte, NC, US
Contact	DAVID M. HERNON
510(k) history	2 submissions · 1 cleared · 2015-2016

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