

**K191200 TULSA-PRO System**Aug 15, 2019  
101 days to decisionK191200 · Product code: **PLP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k191200/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	May 6, 2019
Decision date	Aug 15, 2019
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Profound Medical, Inc.</b>
Location	Mississauga, CA
Contact	Goldy Singh
510(k) history	5 submissions · 5 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191200/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026