

K230692 TULSA-PRO SystemSep 20, 2023
191 days to decisionK230692 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230692/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Mar 13, 2023
Decision date	Sep 20, 2023
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Profound Medical, Inc.
Location	Mississauga, CA
Contact	Nicole Baker
510(k) history	5 submissions · 5 cleared · 2019-2024

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