

K211858 TULSA-PRO SystemSep 6, 2022
447 days to decisionK211858 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Jun 16, 2021
Decision date	Sep 6, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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