

K240296 Tulsa Pro System (Pad-105)May 9, 2024
98 days to decisionK240296 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Feb 1, 2024
Decision date	May 9, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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