

K202286 Tulsa-Pro SystemSep 16, 2020
35 days to decisionK202286 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Aug 12, 2020
Decision date	Sep 16, 2020
Days to decision	35 days
Third-party review	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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