FDA 510(k) Premarket Notification

K191200 TULSA-PRO System

CLEARED

Aug 15, 2019
101 days to decision

K191200 · Product code: **PLP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k191200/

SUBMISSION DETAILS

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

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