

**K172285 Ablatherm Fusion**Oct 3, 2017  
67 days to decisionK172285 · Product code: **PLP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k172285/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Jul 28, 2017
Decision date	Oct 3, 2017
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edap Technomed, Inc.</b>
Location	Norcross, GA, US
Contact	Hugo Embert
510(k) history	5 submissions · 5 cleared · 2001-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172285/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026