

**K172721 FOCAL ONE**Jun 7, 2018  
272 days to decisionK172721 · Product code: **PLP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k172721/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Sep 8, 2017
Decision date	Jun 7, 2018
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172721/> 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