

K231378 Exablate Model 2100V1, Exablate Prostate System, Exablate MRgFUS, Exablate 2100V1 Type 3.0Oct 30, 2023
171 days to decisionK231378 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	May 12, 2023
Decision date	Oct 30, 2023
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Insightec , Ltd.
Location	Tirat Carmel, IL
Contact	Inbal Ben Tzvi
Website	http://www.InSightec.com
510(k) history	1 submissions · 1 cleared · 2023-2023

Insightec, Ltd. is a medical device company specializing in Gastroenterology & Urology devices, with a manufacturing facility in Tirat Carmel, IL. The company develops focused ultrasound technology for precision surgical applications. Insightec has received FDA 510(k) clearance from total submission. The company's regulatory activity occurred in 2023. This represents a historical record, as the company has not received clearances in more than five years. The company's cleared devices include the Exablate Model 2100V1, Exablate Prostate System, and Exablate MRgFUS platform...

REGULATORY CONSULTANT

Consulting firm	Insightec, Inc.
Contact	Nadir Alikacem

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k231378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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