FDA 510(k) Premarket Notification

K212150 Exablate Prostate System

CLEARED

Nov 23, 2021
137 days to decision

K212150 · Product code: **PLP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k212150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Jul 9, 2021
Decision date	Nov 23, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**InSightec, Inc.**
Location	Dallas, TX, US
Contact	Nadir Alikacem
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT01657942

Focal MR-Guided Focused Ultrasound Treatment of Localized Intermediate Risk Prostate Lesions

Status	Completed
Enrollment	101 patients (actual)
Study sites	9 sites
Condition studied	Localized Intermediate Risk Prostate Lesions
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2021
Sponsor	InSightec (Industry)

Primary outcome

Number of Device and Procedure Related Adverse Events

Secondary outcome

Prostate Specific Antigen (PSA)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01657942