FDA 510(k) Premarket Notification

K252435 Magnetic Surgical System

CLEARED

Sep 26, 2025
56 days to decision

K252435 · Product code: **PNL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Surgical System (PNL)
Date received	Aug 1, 2025
Decision date	Sep 26, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Levita Magnetics International Corp**
Location	San Mateo, CA, US
Contact	Donielle Baudin
510(k) history	8 submissions · 7 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Domecus Consulting Services**
Contact	Cindy Domecus

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

CLINICAL EVIDENCE - NCT02049983

Levita Magnetic Grasper Device Safety and Performance Study

Status	Completed
Enrollment	50 patients (actual)
Study sites	3 sites
Condition studied	Benign Gallbladder Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 1, 2015
Sponsor	Levita Magnetics (Industry)

Primary outcome

Safety Assessment of AEs

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02049983