

K232865 Magseed Pro Magnetic Marker System

Jun 28, 2024
287 days to decisionK232865 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232865/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Sep 15, 2023
Decision date	Jun 28, 2024
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Endomagnetics Ltd.,
Location	Cambridge, GB
Contact	Mehryar Behizad
510(k) history	5 submissions · 5 cleared · 2016-2024

CLINICAL EVIDENCE - NCT05142787

Magseed Pro(R)/ Sentimag(R) Gen3

Status	Recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	224 patients (estimated)
Study sites	6 sites
Condition studied	Breast Cancer
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jun 30, 2026
Sponsor	Endomagnetics Ltd. (Industry)

Primary outcome

The primary endpoints are the retrieval rates of the Magseed Pro® marker with the target lesion within the initial excised specimen for A.) axillary lymph nodes B.) breast lesions A.) axillary lymph nodes. B.) breast lesions

Secondary outcome

Tissue response (unexpected and expected)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05142787
