FDA 510(k) Premarket Notification

K222832 Sentimag System

CLEARED

Jan 21, 2023
123 days to decision

K222832 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222832/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Sep 20, 2022
Decision date	Jan 21, 2023
Days to decision	123 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