FDA 510(k) Premarket Notification

K253803 MILAN System

CLEARED

Jun 2, 2026
186 days to decision

K253803 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 28, 2025
Decision date	Jun 2, 2026
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lumenis Be, Ltd.**
Location	Yokneam, IL
Contact	Shlomit Segman
510(k) history	6 submissions · 6 cleared · 2022-2026