

**K253803 MILAN System**Jun 2, 2026  
186 days to decisionK253803 · Product code: **GEI** · General & Plastic SurgerySource: <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	<b>Lumenis Be, Ltd.</b>
Location	Yokneam, IL
Contact	Shlomit Segman
510(k) history	6 submissions · 6 cleared · 2022-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253803/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026