

**K130793 NEWA SKIN THERAPY SYSTEM**Aug 16, 2013  
147 days to decisionK130793 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k130793/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 22, 2013
Decision date	Aug 16, 2013
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endymion Medical, Ltd.</b>
Location	Binyamina, IL
Contact	YORAM LEVY
510(k) history	2 submissions · 2 cleared · 2009-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130793/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026