

**K090399 TRIOS SYSTEM**Jun 10, 2009  
113 days to decisionK090399 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k090399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Feb 17, 2009
Decision date	Jun 10, 2009
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Viora , Ltd.</b>
Location	Jersey City, NJ, US
Contact	JOSEF LUZON
510(k) history	11 submissions · 11 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090399/> 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 22, 2026