

**K082039 SYNCHRO HP PLATFORM**Mar 20, 2009  
245 days to decisionK082039 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k082039/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 2008
Decision date	Mar 20, 2009
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>EI.En Electronic Engineering Spa</b>
Location	Calenzano, IT
Contact	ANDREA TOZZI
510(k) history	27 submissions · 27 cleared · 2007-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082039/> 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 23, 2026