

**K052371 DEPILITE EL-8B SERIES DERMO FLASH SYSTEMS**May 4, 2006  
247 days to decisionK052371 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k052371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 30, 2005
Decision date	May 4, 2006
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hair International Systems USA, Inc.</b>
Location	Newport Beach, CA, US
Contact	CRAIG A MITCHELL
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052371/> 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 30, 2026