

**K173676 A-FIT**Sep 14, 2018  
288 days to decisionK173676 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173676/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 30, 2017
Decision date	Sep 14, 2018
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hironic Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Sangwon Hwang
510(k) history	8 submissions · 8 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173676/> 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 May 26, 2026