

**K201773 PICOHI**Oct 19, 2021  
477 days to decisionK201773 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201773/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 29, 2020
Decision date	Oct 19, 2021
Days to decision	477 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hironic Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Su Yeon Back
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/k201773/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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