

**K171648 BM.IRIS**Sep 8, 2017  
95 days to decisionK171648 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 5, 2017
Decision date	Sep 8, 2017
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bluecore Co., Ltd.</b>
Location	Haeundae-Gu, KR
Contact	Bill Choi
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171648/> 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 31, 2026