

K161503 ORIONAug 26, 2016
86 days to decisionK161503 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 1, 2016
Decision date	Aug 26, 2016
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Yerim Engineering Co., Ltd.
Location	Gimpo-Si, KR
Contact	Won Gil Jeon
510(k) history	1 submissions · 1 cleared · 2016-2016

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