

K180224 ELEMENT-TLMar 15, 2018
48 days to decisionK180224 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 26, 2018
Decision date	Mar 15, 2018
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elemenic Co., Ltd.
Location	Bucheon-Si, KR
Contact	Jo Won Ju
510(k) history	1 submissions · 1 cleared · 2018-2018

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