

K182663 Nobleen Long Pulsed Alexandrite & Nd: YAG Laser SystemNov 30, 2018
66 days to decisionK182663 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2018
Decision date	Nov 30, 2018
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Finemec Co., Ltd.
Location	Seoul, KR
Contact	William H. McGrail
510(k) history	2 submissions · 2 cleared · 2015-2018

REGULATORY CONSULTANT

Consulting firm	Mcgrail Consulting, LLC
Contact	William H. McGrail

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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