

K173359 Fractional CO2 Surgical Laser SystemJul 5, 2018
252 days to decisionK173359 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 26, 2017
Decision date	Jul 5, 2018
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ami, Inc.
Location	Seoul, KR
Contact	Hae Youn Lee
510(k) history	3 submissions · 3 cleared · 2017-2024

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