

K210964 Resonic Rapid Acoustic Pulse DeviceApr 27, 2021
27 days to decisionK210964 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 31, 2021
Decision date	Apr 27, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Soliton, Inc.
Location	Houston, TX, US
Contact	Leslie Honda
510(k) history	5 submissions · 5 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

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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