

K201801 Rapid Acoustic Pulse DeviceJan 29, 2021
213 days to decisionK201801 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 30, 2020
Decision date	Jan 29, 2021
Days to decision	213 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 Lpp
Contact	Janice M Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026