

K190542 Soliton Acoustic Wave DeviceMay 24, 2019
81 days to decisionK190542 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 4, 2019
Decision date	May 24, 2019
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190542/> 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