FDA 510(k) Premarket Notification

K190542 Soliton Acoustic Wave Device

CLEARED

May 24, 2019
81 days to decision

K190542 · 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