FDA 510(k) Premarket Notification

K201801 Rapid Acoustic Pulse Device

CLEARED

Jan 29, 2021
213 days to decision

K201801 · Product code: **GEX** · General & Plastic Surgery
Source: 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