FDA 510(k) Premarket Notification

K212502 Resonic Rapid Acoustic Pulse Device

CLEARED

Nov 5, 2021
88 days to decision

K212502 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212502/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2021
Decision date	Nov 5, 2021
Days to decision	88 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