FDA 510(k) Premarket Notification

K210964 Resonic Rapid Acoustic Pulse Device

CLEARED

Apr 27, 2021
27 days to decision

K210964 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210964/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 31, 2021
Decision date	Apr 27, 2021
Days to decision	27 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