FDA 510(k) Premarket Notification

CLEARED

K233804 Resonic Rapid Acoustic Pulse Device

Feb 1, 2024
64 days to decision

K233804 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233804/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 29, 2023
Decision date	Feb 1, 2024
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zeltiq Aesthetics, Inc.**
Location	Pleasanton, CA, US
Contact	Vicky Chai
510(k) history	13 submissions · 13 cleared · 2012-2024