FDA 510(k) Premarket Notification

K101916 JOULE MULTI-PLATFORM SYSTEM

CLEARED

Mar 18, 2011
252 days to decision

K101916 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k101916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 9, 2010
Decision date	Mar 18, 2011
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sciton, Inc**
Location	Palo Alto, CA, US
Contact	JAY M PATEL
510(k) history	23 submissions · 23 cleared · 2000-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k101916/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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