FDA 510(k) Premarket Notification

K181614 Sterling Supreme Diode Laser

CLEARED

Sep 10, 2019
448 days to decision

K181614 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k181614/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 19, 2018
Decision date	Sep 10, 2019
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**CAO Group, Inc.**
Location	West Jordan, UT, US
Contact	Robert K. Larsen
Website	https://www.caogroup.com
510(k) history	31 submissions · 31 cleared · 2001-2026