FDA 510(k) Premarket Notification

K192617 Gemini 810+980 Soft Tissue Laser

CLEARED

Feb 20, 2020
150 days to decision

K192617 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 23, 2019
Decision date	Feb 20, 2020
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Azena Medical, LLC**
Location	Walnut Creek, CA, US
Contact	Lindsay Tilton
510(k) history	4 submissions · 4 cleared · 2015-2026