FDA 510(k) Premarket Notification

K213889 PicoStar

CLEARED

Apr 22, 2022
130 days to decision

K213889 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2021
Decision date	Apr 22, 2022
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Asclepion Laser Technologies GmbH**
Location	Chelmsford, MA, US
Contact	Carolin Kuehling
510(k) history	29 submissions · 29 cleared · 2004-2026