FDA 510(k) Premarket Notification

K220268 Picosecond Laser System (Model PS10-A and PS10-B)

CLEARED

Aug 23, 2022
204 days to decision

K220268 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 31, 2022
Decision date	Aug 23, 2022
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Adss Development Co., Ltd.**
Location	Beijing, CN
Contact	Song Ying
510(k) history	10 submissions · 10 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov