FDA 510(k) Premarket Notification

K222751 LED Light Therapy Device, KN-7000L

CLEARED

Feb 1, 2023
142 days to decision

K222751 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 12, 2022
Decision date	Feb 1, 2023
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xuzhou Kernel Medical Equipment Co., Ltd.**
Location	Shanghai, CN
Contact	Cuiling Xi
510(k) history	8 submissions · 8 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Junyi Information Technology Co., Ltd.**
Contact	Shanfeng Jiang

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