

K242977 308nm Excimer Phototherapy Device (CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K)

Feb 6, 2025
133 days to decision

K242977 · Product code: **FTC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242977/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Sep 26, 2024
Decision date	Feb 6, 2025
Days to decision	133 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	Che Gang
510(k) history	8 submissions · 8 cleared · 2014-2025

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Device record: <https://www.510kdatabase.net/k242977/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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