

K253828 Medical Alexandrite and Nd:YAG laser Therapy System (CM11LP)Feb 27, 2026
88 days to decisionK253828 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 1, 2025
Decision date	Feb 27, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing HuaCheng Taike Technology Co., Ltd.
Location	Beijing, CN
Contact	Wang Peng
510(k) history	3 submissions · 3 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Tianjin Xinnuocheng Medical Technology Co., LTD.
Contact	Lena Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026