CLEARED

Jan 30, 2026
60 days to decision

K253833 Facial & Body Beauty Device (model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507)

K253833 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Dec 1, 2025
Decision date	Jan 30, 2026
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Jianchao Intelligent Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Fred Li
510(k) history	4 submissions · 4 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Riley Chen

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