

**K223544 LED light therapy mask (FM-01, FM-02, FM-03)**Feb 23, 2023  
90 days to decisionK223544 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223544/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Nov 25, 2022
Decision date	Feb 23, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangdong Newdermo Biotech Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Annie Cai
510(k) history	2 submissions · 2 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223544/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026