

**K213024 Oren LED Perioral Light Therapy System**Dec 22, 2021  
92 days to decisionK213024 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213024/>**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	Sep 21, 2021
Decision date	Dec 22, 2021
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Kaiyan Medical CO , Ltd.</b>
Location	Shenzhen, CN
Contact	Alain Dijkstra
510(k) history	5 submissions · 5 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213024/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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