

**K221775 LED Light Therapy Mask (model: MK-78, MK-04, MK66-H, MK66R-B, EL00003)**Dec 20, 2022  
182 days to decisionK221775 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221775/>**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	Jun 21, 2022
Decision date	Dec 20, 2022
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Light Tree Ventures Europe B.V.</b>
Location	Den Haag, NL
Contact	Kim Laurens
510(k) history	12 submissions · 12 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Kaiyan Medical Equipment Co., Ltd.</b>
Contact	Alain Dijkstra

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221775/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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