

**K221946 LED Light Therapy Mask (model: MK66R-B)**Nov 22, 2022  
140 days to decisionK221946 · Product code: **OHS** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k221946/>**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	Jul 5, 2022
Decision date	Nov 22, 2022
Days to decision	140 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	Alain Dijkstra
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](https://accessdata.fda.gov)

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