

**K253054 LED Light Therapy Mask (M19, M19-1, M19-2, M19-3, M19-5, M19-6)**Dec 19, 2025  
88 days to decisionK253054 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253054/>**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 22, 2025   |
| Decision date         | Dec 19, 2025   |
| Days to decision      | 88 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shenzhen Xinlong Precision Plastic Mold Products Co., Ltd.</b> |
| Location       | Shenzhen, CN  |
| Contact        | Tianfei He  |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025                             |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Feiyong Drug &amp; Medical Consulting Technical Service Group</b> |
| Contact         | Tracy Che  |

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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