

K213184 MZ Skin LightMAX Supercharged LED Mask 2.0Nov 23, 2021
55 days to decisionK213184 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213184/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Over-the-counter Powered Light Based Laser For Acne (OLP) |
| Date received | Sep 29, 2021 |
| Decision date | Nov 23, 2021 |
| Days to decision | 55 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mz Skin |
| Location | London, GB |
| Contact | Maryam Zamani |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | iSMART Developments, Ltd. |
| Contact | Susan D'Arcy |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213184/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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