FDA 510(k) Premarket Notification

# K230342 Phototherapy System (OL-PDT950)

**CLEARED**

Aug 16, 2023
189 days to decision

K230342 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230342/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Feb 8, 2023 |
| Decision date | Aug 16, 2023 |
| Days to decision | 189 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shanghai Omni Laser Skinology Co., Ltd.** |
| Location | Shanghai, CN |
| Contact | Avril Ouyang |
| 510(k) history | 3 submissions · 3 cleared · 2023-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **New Risen Enterprise Management Consulting Co.,Ltd** |
| Contact | Helen Nan |

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