FDA 510(k) Premarket Notification

K221523 Tanning Lamp

CLEARED

Feb 15, 2023
265 days to decision

K221523 · Product code: **LEJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Booth, Sun Tan (LEJ)
Date received	May 26, 2022
Decision date	Feb 15, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Unilam Co., Ltd.**
Location	Ulsan Gwangyeogsi, KR
Contact	Y B Cho
510(k) history	2 submissions · 2 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	**Allura Medical Solutions, Inc.**
Contact	Edward Park

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221523/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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