

**K210004 i8 Tanning Booth**Dec 10, 2021  
340 days to decisionK210004 · Product code: **FTC** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k210004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Jan 4, 2021
Decision date	Dec 10, 2021
Days to decision	340 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultrasun International B.V.</b>
Location	Hengelo, NL
Contact	Tim Leusink
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bentley Biomedical Consulting, LLC</b>
Contact	Shepard G. Bentley

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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