

**K011197 DERMACLEAR UV-B PHOTOTHERAPY SYSTEM**Dec 14, 2001  
239 days to decisionK011197 · Product code: **FTC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Apr 19, 2001
Decision date	Dec 14, 2001
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumenis</b>
Location	Pleasanton, CA, US
Contact	C. ROBERT PAYNE JR.
Website	<a href="http://www.lumenis.com/">http://www.lumenis.com/</a>
510(k) history	5 submissions · 5 cleared · 2001-2010

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011197/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 21, 2026