

**K850493 SUNSHOWER MODEL HU-01-12L**Feb 28, 1985  
20 days to decisionK850493 · Product code: **FTC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k850493/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Feb 8, 1985
Decision date	Feb 28, 1985
Days to decision	20 days
Third-party review	No

**APPLICANT**

---

Company	<b>Sunthetic Engineering, Inc.</b>
Location	Marion, IA, US
Contact	DEAN MONTOUR
510(k) history	2 submissions · 2 cleared · 1985-1986

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850493/>; 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 July 8, 2026