

K183539 Ergoline Sunrise 7200 Hybrid TechnologyApr 8, 2019
109 days to decisionK183539 · Product code: **LEJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Booth, Sun Tan (LEJ)
Date received	Dec 20, 2018
Decision date	Apr 8, 2019
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jk Holding GmbH
Location	Windhagen, DE
Contact	Juergen Gerstenmeier
510(k) history	6 submissions · 6 cleared · 2015-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183539/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026