FDA 510(k) Premarket Notification

CLEARED

K180555 Ergoline Prestige 1600 Hybrid Performance

Oct 11, 2018
224 days to decision

K180555 · Product code: **LEJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180555/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Booth, Sun Tan (LEJ)
Date received	Mar 1, 2018
Decision date	Oct 11, 2018
Days to decision	224 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.net
Device record: https://www.510kdatabase.net/k180555/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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