

**K190173 Ergoline Inspiration 550 Hybrid Technology / Sound,
Ergoline Inspiration 550 Hybrid Technology / AC / Sound,
Ergoline Planet Fitness 42/4 Hybrid Light Technology / Sound**

May 10, 2019
98 days to decision

K190173 · Product code: LEJ · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190173/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Booth, Sun Tan (LEJ)
Date received	Feb 1, 2019
Decision date	May 10, 2019
Days to decision	98 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/k190173/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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