

K220500 Ergoline Vitality Total Light 3, Planet Fitness 50/4 TLT by Ergoline, Planet Fitness 42/3 TLT by Ergoline, Ergoline Vitality Hybrid Light 3, Ergoline Vitality Hybrid Light, Planet Fitness 50/4 HLT by Ergoline, Planet Fitness 46/3 HLT by Ergoline, Ergoline Vitality Pure Light 3, Ergoline Vitality Pure Light, Planet Fitness 50/4 PLT III by Ergoline, Planet Fitness 50/4 PLT by Ergoline, Planet Fitness 46/3 PLT by Ergoline, Planet Fitness 42/3 PLT by Ergoline

Jul 1, 2022
129 days to decision

K220500 · Product code: LEJ · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k220500/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Booth, Sun Tan (LEJ)
Date received	Feb 22, 2022
Decision date	Jul 1, 2022
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	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/k220500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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