FDA 510(k) Premarket Notification

CLEARED

K191881 KBL 7000 alpha hybridSun, KBL 7900 alpha hybridSun, KBL 8000 alpha hybridSun

Oct 28, 2019
105 days to decision

K191881 · Product code: **LEJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Booth, Sun Tan (LEJ)
Date received	Jul 15, 2019
Decision date	Oct 28, 2019
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kbl GmbH**
Location	Dernbach, DE
Contact	Ralf de Andreis
510(k) history	1 submissions · 1 cleared · 2019-2019