FDA 510(k) Premarket Notification

K220300 OTOPLAN

CLEARED

Jun 24, 2022
142 days to decision

K220300 · Product code: **QQE** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k220300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Management Software For Planning Of Otologic And Neurotologic Procedures (QQE)
Date received	Feb 2, 2022
Decision date	Jun 24, 2022
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cascination AG**
Location	Bern, CH
Contact	Jean-Francois Clemence
510(k) history	6 submissions · 6 cleared · 2015-2025