

K203486 OtoplanAug 20, 2021
266 days to decisionK203486 · Product code: **QQE** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k203486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Management Software For Planning Of Otologic And Neurotologic Procedures (QQE)
Date received	Nov 27, 2020
Decision date	Aug 20, 2021
Days to decision	266 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203486/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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