

K221184 ORiGO SystemNov 2, 2022
191 days to decisionK221184 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k221184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Apr 25, 2022
Decision date	Nov 2, 2022
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bien-Air Surgery SA
Location	Le Noirmont, CH
Contact	Jonas Guerdat
510(k) history	5 submissions · 5 cleared · 2009-2022

REGULATORY CONSULTANT

Consulting firm	Ken Block Consulting, LLC
Contact	Yulia Nikova

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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