

K220097 PRESIDENT The OriginalJan 13, 2022
1 days to decisionK220097 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k220097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jan 12, 2022
Decision date	Jan 13, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Colt?ne/Whaledent AG
Location	Altst?ten, CH
Contact	Katrin Ader
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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