

K193301 coDiagnostiXJun 21, 2021
570 days to decisionK193301 · Product code: **DZJ** · Dental
Source: <https://www.510kdatabase.net/k193301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Nov 29, 2019
Decision date	Jun 21, 2021
Days to decision	570 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dental Wings GmbH
Location	Chemnitz, DE
Contact	Angelika Hähnel
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer M. Jackson

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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