

K220648 OMF ASP SystemAug 11, 2022
157 days to decisionK220648 · Product code: **DZJ** · Dental
Source: <https://www.510kdatabase.net/k220648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Mar 7, 2022
Decision date	Aug 11, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vha Dean
Location	Washington, DC, US
Contact	Beth Ripley
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Lg Strategies, LLC
Contact	Laura Gilmour

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026