FDA 510(k) Premarket Notification

K220648 OMF ASP System

CLEARED

Aug 11, 2022
157 days to decision

K220648 · 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