

K220366 EmbedMedSep 30, 2022
234 days to decisionK220366 · Product code: **DZJ** · DentalSource: <https://www.510kdatabase.net/k220366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Feb 8, 2022
Decision date	Sep 30, 2022
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Lifeprints UK , Ltd.
Location	West Derby, Liverpool, Merseyside, GB
Contact	Henry Pinchbeck
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Olympus Regulatory Solutions
Contact	Sam Murray

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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