

K210828 DIOnavi-Denture02Mar 23, 2021
4 days to decisionK210828 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k210828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 19, 2021
Decision date	Mar 23, 2021
Days to decision	4 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dio Corporation
Location	Los Angeles, CA, US
Contact	Ji-Ae Park
510(k) history	14 submissions · 14 cleared · 2010-2023

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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