

K212509 OSSIX BreezeJul 18, 2022
343 days to decisionK212509 · Product code: **NPL** · Dental
Source: <https://www.510kdatabase.net/k212509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Aug 9, 2021
Decision date	Jul 18, 2022
Days to decision	343 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Datum Dental, Ltd.
Location	Lod, IL
Contact	Arie Goldlust
510(k) history	4 submissions · 4 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US Lpp
Contact	Janice Hogan

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

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