

K231513 Oral MatrixFeb 16, 2024
267 days to decisionK231513 · Product code: **NPL** · Dental
Source: <https://www.510kdatabase.net/k231513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	May 25, 2023
Decision date	Feb 16, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Biosis Healing Biological Technology Co., Ltd.
Location	Beijing, CN
Contact	Ting Jiang
510(k) history	7 submissions · 7 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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