

K200623 OssGuideOct 2, 2020
207 days to decisionK200623 · Product code: **NPL** · Dental
Source: <https://www.510kdatabase.net/k200623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Mar 9, 2020
Decision date	Oct 2, 2020
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sk Bioland Co., Ltd.
Location	Cheongju-Si, KR
Contact	Yeonjeong Chae
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Wise Company, Inc.
Contact	Sanglok Lee

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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