

K230091 THE CoverOct 6, 2023
267 days to decisionK230091 · Product code: **NPL** · DentalSource: <https://www.510kdatabase.net/k230091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Jan 12, 2023
Decision date	Oct 6, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Purgo Biologics, Inc.
Location	Seongnam-Si, KR
Contact	Byungsun Kim
510(k) history	6 submissions · 6 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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