

K242817 Jason membraneDec 12, 2025
450 days to decisionK242817 · Product code: **NPL** · DentalSource: <https://www.510kdatabase.net/k242817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Sep 18, 2024
Decision date	Dec 12, 2025
Days to decision	450 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Botiss Biomaterials GmbH
Location	Zossen, DE
Contact	Thomas Unsoeld
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242817/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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