FDA 510(k) Premarket Notification

K242817 Jason membrane

CLEARED

Dec 12, 2025
450 days to decision

K242817 · Product code: **NPL** · Dental
Source: 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