FDA 510(k) Premarket Notification

K071555 FORTAGEN ORAL MEMBRANE

CLEARED

Aug 30, 2007
84 days to decision

K071555 · Product code: **NPL** · Dental
Source: https://www.510kdatabase.net/k071555/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Jun 7, 2007
Decision date	Aug 30, 2007
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Organogenesis, Inc.**
Location	Canton, MA, US
Contact	PATRICK R BILBO
510(k) history	12 submissions · 12 cleared · 1997-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k071555/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026