

K242179 Synea Fusion Handpieces (Intensiv & Profin)Feb 28, 2025
218 days to decisionK242179 · Product code: **EFB** · DentalSource: <https://www.510kdatabase.net/k242179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jul 25, 2024
Decision date	Feb 28, 2025
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	W&H Dentalwerk B?rmoos GmbH
Location	Buermoos, AT
Contact	Gerhard Weidler
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242179/> 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 13, 2026