

K233158 Copra Smile, Copra Supreme HyperionJun 20, 2024
267 days to decisionK233158 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k233158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 27, 2023
Decision date	Jun 20, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Whitepeaks Dental Solutions GmbH
Location	Essen, DE
Contact	Oliver Puckert
510(k) history	3 submissions · 3 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Blackwell Device Consulting
Contact	Angela Blackwell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233158/> 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 14, 2026