

K232498 UltraSeal XT plus - Bioprotection by Nobio, UltraSeal XT hydro - Bioprotection by NobioAug 18, 2023
1 days to decisionK232498 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k232498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Aug 17, 2023
Decision date	Aug 18, 2023
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ultradent Product, Inc.
Location	South Jordan, UT, US
Contact	Ruth Gardner
510(k) history	2 submissions · 2 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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/k232498/> 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 25, 2026