

K213244 Accusil Dental Impression Materials (Accusil Light Body Regular and Fast Set, Accusil Heavy Body Regular and Fast Set, Accusil Monophase Regular and Fast Set, Accusil Putty Regular and Fast Set, Accusil Bite Registration)Sep 9, 2022
344 days to decisionK213244 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k213244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Sep 30, 2021
Decision date	Sep 9, 2022
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prevest Denpro Limited
Location	Bari Brahmana, IN
Contact	Atul Modi
510(k) history	7 submissions · 7 cleared · 2021-2024

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/k213244/> 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