

K163480 Renamel NANO +plusFeb 24, 2017
74 days to decisionK163480 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k163480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 12, 2016
Decision date	Feb 24, 2017
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cosmedent, Inc.
Location	Chicago, IL, US
Contact	Hiren Patel
510(k) history	28 submissions · 28 cleared · 1986-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163480/> 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