

K191980 CLEARFIL MAJESTY ES FlowNov 18, 2019
117 days to decisionK191980 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k191980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 24, 2019
Decision date	Nov 18, 2019
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Kuraray Noritake Dental, Inc.
Location	New York, NY, US
Contact	Yasujiro Ohara
510(k) history	32 submissions · 32 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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