

**K220369 Esthetic Colorant**Sep 23, 2022  
227 days to decisionK220369 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k220369/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Feb 8, 2022
Decision date	Sep 23, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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