

K191903 BruxZir GT (Gum Tissue) ColorNov 22, 2019
129 days to decisionK191903 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k191903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jul 16, 2019
Decision date	Nov 22, 2019
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prismatik Dentalcraft, Inc.
Location	Newport Beach, CA, US
Contact	Mythili Reguraman
510(k) history	57 submissions · 57 cleared · 2010-2026

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