

**K201799 CleaniCal**Feb 12, 2021  
227 days to decisionK201799 · Product code: **EJK** · DentalSource: <https://www.510kdatabase.net/k201799/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	Jun 30, 2020
Decision date	Feb 12, 2021
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>Maruchi</b>
Location	Fullerton, CA, US
Contact	Jang Sung Wook
510(k) history	8 submissions · 8 cleared · 2012-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201799/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026