

K212283 BioRoot Flow 0.5g, BioRoot Flow 2gSep 16, 2021
57 days to decisionK212283 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k212283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jul 21, 2021
Decision date	Sep 16, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Septodont
Location	Washington, DC, US
Contact	Kimty Bui Van
510(k) history	9 submissions · 9 cleared · 2003-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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