

**K192530 Surefil one Self-adhesive Composite Hybrid**Jan 23, 2020  
129 days to decisionK192530 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k192530/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 16, 2019
Decision date	Jan 23, 2020
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsply Sirona</b>
Location	York, PA, US
Contact	Karl Nittinger
Website	<a href="https://www.dentsplysirona.com">https://www.dentsplysirona.com</a>
510(k) history	65 submissions · 65 cleared · 2016-2026

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...

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Device record: <https://www.510kdatabase.net/k192530/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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