

**K240446 Calx-O, Calcium Hydroxide Powder, Calahyd RC, CeraSeal B, MTA, Rootfyx, Sealmax R, Sealmax +**Jul 30, 2024  
166 days to decisionK240446 · Product code: **KIF** · Dental  
Source: <https://www.510kdatabase.net/k240446/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Feb 15, 2024
Decision date	Jul 30, 2024
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shiva Products</b>
Location	Palghar, IN
Contact	Urvi Doshi
510(k) history	1 submissions · 1 cleared · 2024-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240446/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026