

**K222961 Harvest Conceal ZR Block Out**Jun 2, 2023  
248 days to decisionK222961 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k222961/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 27, 2022
Decision date	Jun 2, 2023
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Harvest Dental Products, LLC</b>
Location	Sarasota, FL, US
Contact	Colleen Boswell
510(k) history	5 submissions · 5 cleared · 2014-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222961/> 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 27, 2026