

**K191794 Vintage Art Universal**Oct 3, 2019  
92 days to decisionK191794 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k191794/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | Jul 3, 2019                        |
| Decision date         | Oct 3, 2019                        |
| Days to decision      | 92 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Shofu Dental Corporation</b>         |
| Location       | San Marcos, CA, US                      |
| Contact        | Mauro Malzyner                          |
| 510(k) history | 38 submissions · 38 cleared · 2011-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191794/> 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 June 28, 2026