

K221510 TrusFIL-Flow Flowable Composite RestorativeOct 12, 2022
141 days to decisionK221510 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k221510/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | May 24, 2022 |
| Decision date | Oct 12, 2022 |
| Days to decision | 141 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Rizhao Huge Biomaterials Company, Ltd. |
| Location | Rizhao City, CN |
| Contact | Maggie Zheng |
| 510(k) history | 13 submissions · 13 cleared · 2020-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221510/> 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 25, 2026