

**K221242 Vsmilehappyzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank**Jul 29, 2022  
88 days to decisionK221242 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k221242/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | May 2, 2022                        |
| Decision date         | Jul 29, 2022                       |
| Days to decision      | 88 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hunan Vsmile Biotechnology Co., Ltd.</b> |
| Location       | Changsha, CN                                |
| Contact        | Xiaomi Tang                                 |
| 510(k) history | 2 submissions · 2 cleared · 2022-2024       |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Guangzhou Junyi Information Technology Co., Ltd.</b> |
| Contact         | Shanfeng Jiang  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221242/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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