

**K161652 DIAZIR**Nov 28, 2017  
531 days to decisionK161652 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k161652/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | Jun 15, 2016                       |
| Decision date         | Nov 28, 2017                       |
| Days to decision      | 531 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Zxtgy (Beijing) Technology Co., Ltd.</b> |
| Location       | Beijing, CN                                 |
| Contact        | N/A N/A                                     |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161652/> 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 31, 2026