

**K162853 Bonafix TWO - Dental Implant System**Jul 14, 2017  
276 days to decisionK162853 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k162853/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Oct 11, 2016                         |
| Decision date         | Jul 14, 2017                         |
| Days to decision      | 276 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bonafix Surgical and Dental Implants</b> |
| Location       | Delray Beach, FL, US                        |
| Contact        | Juan Tezak                                  |
| 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/k162853/> 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 1, 2026