

**K140806 IBS IMPLANT SYSTEM**Mar 23, 2015  
356 days to decisionK140806 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k140806/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Apr 1, 2014                          |
| Decision date         | Mar 23, 2015                         |
| Days to decision      | 356 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Statement                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Innobiosurg Co., Ltd.</b>            |
| Location       | Echo, AZ, US                            |
| Contact        | CHARLIE MACK                            |
| 510(k) history | 15 submissions · 15 cleared · 2015-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140806/> 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 26, 2026