

**K151599 iSy Implant System**Oct 2, 2015  
112 days to decisionK151599 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k151599/>**SUBMISSION DETAILS**

---

|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Jun 12, 2015                         |
| Decision date         | Oct 2, 2015                          |
| Days to decision      | 112 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Altatec GmbH</b>                     |
| Location       | Reno, NV, US                            |
| Contact        | Colleen Boswell                         |
| 510(k) history | 14 submissions · 14 cleared · 2006-2020 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151599/> 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 20, 2026