

**K051501 ZIRACE**Oct 19, 2005  
135 days to decisionK051501 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k051501/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received         | Jun 6, 2005                                 |
| Decision date         | Oct 19, 2005                                |
| Days to decision      | 135 days                                    |
| Third-party review    | No  |
| Summary / Statement   | Summary                                     |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Acucera, Inc.</b>                  |
| Location       | Seul, KR                              |
| Contact        | KYUNG-BIN LEE                         |
| 510(k) history | 2 submissions · 2 cleared · 2005-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051501/> 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 28, 2026