

**K060640 DIGIREX DIGITAL DENTAL RADIOGRAPHY SYSTEM**Apr 24, 2006  
45 days to decisionK060640 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k060640/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Unit, X-ray, Extraoral With Timer (EHD) |
| Date received         | Mar 10, 2006                            |
| Decision date         | Apr 24, 2006                            |
| Days to decision      | 45 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dentamerica</b>                    |
| Location       | Industry, CA, US                      |
| Contact        | ERIC HUANG                            |
| 510(k) history | 4 submissions · 4 cleared · 1996-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060640/> 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 18, 2026