

**K082167 PORTABLE X-RAY SYSTEM, MODELS DIOX-602,  
PROX**Sep 26, 2008  
57 days to decisionK082167 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k082167/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Unit, X-ray, Extraoral With Timer (EHD) |
| Date received         | Jul 31, 2008                            |
| Decision date         | Sep 26, 2008                            |
| Days to decision      | 57 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Digimed Corporation</b>            |
| Location       | Salt Lake City, UT, US                |
| Contact        | SHIN KUK YOO                          |
| 510(k) history | 2 submissions · 2 cleared · 2008-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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