

**K134055 ADX4000W**May 9, 2014  
129 days to decisionK134055 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k134055/>**SUBMISSION DETAILS**

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|                       |                                                |
|-----------------------|------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Special                                        |
| Device classification | System, X-ray, Extraoral Source, Digital (MUH) |
| Date received         | Dec 31, 2013                                   |
| Decision date         | May 9, 2014                                    |
| Days to decision      | 129 days                                       |
| Third-party review    | No                                             |
| Summary / Statement   | Summary                                        |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dexcowin Co., Ltd.</b>             |
| Location       | Seoul, KR                             |
| Contact        | Claude Berthoin                       |
| 510(k) history | 5 submissions · 5 cleared · 2009-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k134055/> 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 16, 2026