

**K013054 KONICA DIRECT DIGITIZER REGIUS MODEL 350**Mar 1, 2002  
171 days to decisionK013054 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k013054/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received         | Sep 11, 2001   |
| Decision date         | Mar 1, 2002  |
| Days to decision      | 171 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Konica Minolta Medical &amp; Graphic, Inc.</b> |
| Location       | Hachioji-Shi Tokyo, JP                            |
| Contact        | KOJI KUBO   |
| 510(k) history | 27 submissions · 27 cleared · 2002-2013           |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013054/> 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 17, 2026