

**K120246 KODAK DIRECTVIEW CR MAMMOGRAPHY SYSTEM  
(USING CARESTREAM CR MAMMOGRAPHY CASSETTE WITH  
SNP-M1 SCREEN)**

Aug 28, 2012  
214 days to decision

K120246 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k120246/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | Full Field Digital, System, X-ray, Mammographic (MUE) |
| Date received         | Jan 27, 2012  |
| Decision date         | Aug 28, 2012  |
| Days to decision      | 214 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Carestream Health, Inc.</b>  |
| Location       | Rochester, NY, US   |
| Contact        | KATHERINE HONSINGER   |
| Website        | <a href="http://www.carestream.com/default.aspx?LangType=1033">http://www.carestream.com/default.aspx?LangType=1033</a> |
| 510(k) history | 48 submissions · 48 cleared · 2008-2025   |

Carestream Health, Inc. is a worldwide provider of medical imaging systems and X-ray imaging solutions. The company operates with a manufacturing facility in Rochester, US and maintains a global service and support network across multiple markets. Carestream has received FDA 510(k) clearances from total submissions since 2008. The company specializes in Radiology devices, which represent 94% of its regulatory submissions. The latest clearance was granted in 2025, demonstrating continued active development and market engagement. Recent cleared devices include digital radio...