

K183245 Carestream DRX-1 System with DRX Plus 2530 DetectorsFeb 8, 2019
79 days to decisionK183245 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k183245/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Nov 21, 2018 |
| Decision date | Feb 8, 2019 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Carestream Health, Inc. |
| Location | Rochester, NY, US |
| Contact | Gina L Maiolo |
| Website | http://www.carestream.com/default.aspx?LangType=1033 |
| 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...

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Device record: <https://www.510kdatabase.net/k183245/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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