FDA 510(k) Premarket Notification

K180809 Eclipse II

CLEARED

Jun 21, 2018
85 days to decision

K180809 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k180809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Mar 28, 2018
Decision date	Jun 21, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carestream Health, Inc.**
Location	Rochester, NY, US
Contact	Diane Koetter
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/k180809/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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