FDA 510(k) Premarket Notification

CLEARED

K163203 Carestream DRX-Evolution

Dec 13, 2016
28 days to decision

K163203 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k163203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 15, 2016
Decision date	Dec 13, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Carestream Health, Inc.**
Location	Rochester, NY, US
Contact	Carolyn L. Wagner
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...