FDA 510(k) Premarket Notification

K192894 Vita Flex CR System with LLI

CLEARED

Feb 18, 2020
130 days to decision

K192894 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k192894/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Oct 11, 2019
Decision date	Feb 18, 2020
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carestream Health, Inc.**
Location	Rochester, NY, US
Contact	Duane Gutowski
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...