

K163157 SmartGridMar 21, 2017
131 days to decisionK163157 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k163157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 10, 2016
Decision date	Mar 21, 2017
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carestream Health
Location	Rochester, NY, US
Contact	Diane Koetter
Website	http://www.carestream.com/default.aspx?LangType=1033
510(k) history	5 submissions · 5 cleared · 2017-2026

Carestream Health is a worldwide provider of X-ray imaging systems and precision coating services. The company is headquartered in Rochester, US. Carestream has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. The company's regulatory track record spans from 2017 to 2026, with its most recent clearance in 2026 demonstrating continued active development and market engagement. The company specializes in digital radiography systems and detectors for medical imaging applications. Product lines include mobile X-ray syste...
