FDA 510(k) Premarket Notification

K183182 Critical Care Suite

CLEARED

Aug 12, 2019
266 days to decision

K183182 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k183182/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Nov 19, 2018
Decision date	Aug 12, 2019
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems, LLC**
Location	Waukesha, WI, US
Contact	Camille Vidal
Website	https://www.gehealthcare.com
510(k) history	104 submissions · 104 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...