

K163619 SIGNA PET/MRFeb 14, 2017
54 days to decisionK163619 · Product code: **OUO** · Radiology
Source: <https://www.510kdatabase.net/k163619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Dec 22, 2016
Decision date	Feb 14, 2017
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems, LLC
Location	Waukesha, WI, US
Contact	Janice M. Sich
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...
