

**K211846 Discovery MI Gen2**Aug 20, 2021  
66 days to decisionK211846 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k211846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jun 15, 2021
Decision date	Aug 20, 2021
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems, LLC</b>
Location	Waukesha, WI, US
Contact	Laura Turner
Website	<a href="https://www.gehealthcare.com">https://www.gehealthcare.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211846/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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