

K213715 Revolution Apex, Revolution Apex Elite, Revolution Apex Plus, Revolution Apex Select, Revolution CT

Dec 17, 2021
23 days to decision

K213715 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213715/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 24, 2021
Decision date	Dec 17, 2021
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Revolution CT ES; Revolution CT with Apex edition; Revolution CT ES with Apex edition

APPLICANT

Company	Ge Medical Systems, LLC
Location	Waukesha, WI, US
Contact	Katelyn Rowley
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...