

K211161 Critical Care Suite with Endotracheal Tube Positing AI algorithm

Oct 29, 2021
193 days to decisionK211161 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k211161/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 19, 2021
Decision date	Oct 29, 2021
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems, LLC
Location	Waukesha, WI, US
Contact	Chris Paulik
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...

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Device record: <https://www.510kdatabase.net/k211161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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