

K200213 Biograph mMR with syngo MR E11P-AP01 system softwareMay 11, 2020
104 days to decisionK200213 · Product code: **OUO** · Radiology
Source: <https://www.510kdatabase.net/k200213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Jan 28, 2020
Decision date	May 11, 2020
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Cordell L. Fields
510(k) history	778 submissions · 778 cleared · 1980-2026

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