

K163234 Biograph mMR with syngo MR E11P system softwareFeb 28, 2017
103 days to decisionK163234 · Product code: **OUO** · Radiology
Source: <https://www.510kdatabase.net/k163234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Nov 17, 2016
Decision date	Feb 28, 2017
Days to decision	103 days
Third-party review	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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