

K161395 SPEC Model M13Jul 6, 2016
48 days to decisionK161395 · Product code: **KXK** · Radiology
Source: <https://www.510kdatabase.net/k161395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	May 19, 2016
Decision date	Jul 6, 2016
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Source Production and Equipment Co., Inc.
Location	Saint Rose, LA, US
Contact	Kelley Richardt
510(k) history	4 submissions · 4 cleared · 2015-2016

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