

K183142 PathVisionXLMar 14, 2019
121 days to decisionK183142 · Product code: **MWP** · Radiology
Source: <https://www.510kdatabase.net/k183142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, X-ray System (MWP)
Date received	Nov 13, 2018
Decision date	Mar 14, 2019
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Faxitron Bioptics, LLC
Location	Tucson, AZ, US
Contact	Ciaran Purdy
510(k) history	5 submissions · 5 cleared · 2012-2019

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