

K173309 Faxitron VisionCTMay 9, 2018
203 days to decisionK173309 · Product code: **MWP** · Radiology
Source: <https://www.510kdatabase.net/k173309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, X-ray System (MWP)
Date received	Oct 18, 2017
Decision date	May 9, 2018
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Faxitron Bioptics, LLC
Location	Tucson, AZ, US
Contact	Douglas C. Wiegman
510(k) history	5 submissions · 5 cleared · 2012-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173309/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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