

K161459 Nexus DRTM Digital X-ray Imaging System (with PaxScan 4336Wv4)

Sep 6, 2016
103 days to decision

K161459 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k161459/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 26, 2016
Decision date	Sep 6, 2016
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems, X-Ray Products-Infimed
Location	Liverpool, NY, US
Contact	Catherine Mulcahy
510(k) history	2 submissions · 2 cleared · 2013-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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