FDA 510(k) Premarket Notification

K190611 VIVIX-S 1751S

CLEARED

Apr 8, 2019
28 days to decision

K190611 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k190611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Mar 11, 2019
Decision date	Apr 8, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vieworks Co., Ltd.**
Location	Gyeonggi-Do, KR
Contact	Jordin Kim
510(k) history	19 submissions · 19 cleared · 2007-2025