

K190611 VIVIX-S 1751SApr 8, 2019
28 days to decisionK190611 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026