

K243449 INFINITT DPSDec 9, 2025
397 days to decisionK243449 · Product code: **QKQ** · Pathology
Source: <https://www.510kdatabase.net/k243449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Pathology Image Viewing And Management Software (QKQ)
Date received	Nov 7, 2024
Decision date	Dec 9, 2025
Days to decision	397 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Infinitt Healthcare Co., Ltd.
Location	Seoul, KR
Contact	Josh Baker
510(k) history	4 submissions · 4 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243449/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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