

K211179 InferRead CT Stroke.AIAug 12, 2021
114 days to decisionK211179 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k211179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Apr 20, 2021
Decision date	Aug 12, 2021
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Infervision Medical Technology Co., Ltd.
Location	Beijing, CN
Contact	Xiaoyan Fan
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Infervision Us, Inc.
Contact	Matt Deng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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