FDA 510(k) Premarket Notification

K211179 InferRead CT Stroke.AI

CLEARED

Aug 12, 2021
114 days to decision

K211179 · 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