FDA 510(k) Premarket Notification

K221716 CINA

CLEARED

Nov 22, 2022
162 days to decision

K221716 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k221716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jun 13, 2022
Decision date	Nov 22, 2022
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avicenna.Ai**
Location	La Ciotat, FR
Contact	Stephane Berger
510(k) history	7 submissions · 7 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

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