FDA 510(k) Premarket Notification

K231273 ArcherQA (V1.0)

CLEARED

Jan 5, 2024
248 days to decision

K231273 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k231273/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 2, 2023
Decision date	Jan 5, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wisdom Technologies., Inc.**
Location	Hefei, CN
Contact	Xie Xu
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Wei Wang**
Contact	Wei Wang

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