

K231273 ArcherQA (V1.0)Jan 5, 2024
248 days to decisionK231273 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026