FDA 510(k) Premarket Notification

K223834 AccuCheck

CLEARED

Jul 20, 2023
210 days to decision

K223834 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k223834/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 22, 2022
Decision date	Jul 20, 2023
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Manteia Technologies Co., Ltd.**
Location	Xiamen, CN
Contact	Yingkai Lin
510(k) history	6 submissions · 6 cleared · 2023-2026