

K260303 See-Mode Augmented Reporting Tool, Breast (SMART-B)

Jul 28, 2026
179 days to decision

K260303 · Product code: QDQ · Radiology
Source: <https://www.510kdatabase.net/k260303/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jan 30, 2026
Decision date	Jul 28, 2026
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	See-Mode Technologies Pty, Ltd.
Location	Melbourne, AU
Contact	Sadaf Monajemi
510(k) history	1 submissions · 1 cleared · 2026-2026