

K213439 FlexBoard™, EagleBoard™, BreastBoard SXTMJun 24, 2022
242 days to decisionK213439 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k213439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 25, 2021
Decision date	Jun 24, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Macromedics BV
Location	Waddinxveen, NL
Contact	Elizabeth Hajos
510(k) history	5 submissions · 5 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213439/> 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 27, 2026