

**K003778 BREAST-BOARD (MULTIPLE)**Jun 8, 2001  
183 days to decisionK003778 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k003778/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 7, 2000
Decision date	Jun 8, 2001
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Arplay Medical S.A.</b>
Location	Izeure, Cote D'Or, FR
Contact	RICHARD BORGI
510(k) history	9 submissions · 9 cleared · 2001-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003778/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026