

K010063 COUCH FOR TOTAL BODY RADIATIONApr 2, 2001
84 days to decisionK010063 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k010063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 8, 2001
Decision date	Apr 2, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010063/> 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 19, 2026