

**K090914 AXXENT BALLOON APPLICATOR, MODEL AB2034,
AB2045, AB2056, AB2057E, AB2067E**Jul 16, 2009
106 days to decisionK090914 · Product code: **JAD** · Radiology
Source: <https://www.510kdatabase.net/k090914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Apr 1, 2009
Decision date	Jul 16, 2009
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xoft, Inc.
Location	Fremont, CA, US
Contact	STEVE LIN
510(k) history	6 submissions · 3 cleared · 2005-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090914/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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