K110729 ASPIRE HD FULL-FIELD DIGITAL MAMMOGRAPHY SYSTEM

CLEARED

Sep 1, 2011
169 days to decision

K110729 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k110729/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Mar 16, 2011
Decision date	Sep 1, 2011
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Medical Systems U.S.A, Inc.**
Location	Stamford, CT, US
Contact	PETER ALTMAN
510(k) history	39 submissions · 39 cleared · 2005-2018