

K010796 AIA-PACK BRCA, ST AIA PACK BRCAAug 16, 2001
153 days to decisionK010796 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k010796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Mar 16, 2001
Decision date	Aug 16, 2001
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tosoh Medics, Inc.
Location	Washington, DC, US
Contact	LOIS NAKAYAMA
510(k) history	41 submissions · 41 cleared · 1990-2002

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