

K012820 AIA-PACK CTNI 2ND-GEN ASSAYDec 14, 2001
113 days to decisionK012820 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k012820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Aug 23, 2001
Decision date	Dec 14, 2001
Days to decision	113 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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