

K092817 POC-AS10 AUTO SAMPLERMar 9, 2010
176 days to decisionK092817 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k092817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Sep 14, 2009
Decision date	Mar 9, 2010
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Otsuka Pharmaceutical Co., Ltd.
Location	Rockville, MD, US
Contact	CYNTHIA A SINCLAIR
Website	http://www.otsuka.co.jp
510(k) history	6 submissions · 6 cleared · 1999-2010

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