

K041148 POCONE INFRARED SPECTROPHOTOMETERJul 15, 2004
73 days to decisionK041148 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k041148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	May 3, 2004
Decision date	Jul 15, 2004
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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