

**K011400 MRSA-SCREEN**

Mar 27, 2002  
324 days to decision

K011400 · Product code: **MYI** · Microbiology  
Source: <https://www.510kdatabase.net/k011400/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI)
Date received	May 7, 2001
Decision date	Mar 27, 2002
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Denka Seiken&amp;apos;S</b>
Location	Tokyo, JP
Contact	KEVIN MANGAN
510(k) history	4 submissions · 4 cleared · 1998-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k011400/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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