

**K081643 DIMENSION TNI FLEX REAGENT CARTRIDGE, AND CTNI SAMPLE DILUENT WITH MODELS, RF621, KD692**

Jul 3, 2008  
21 days to decision

K081643 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k081643/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 12, 2008
Decision date	Jul 3, 2008
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	YUK-TING LEWIS
510(k) history	92 submissions · 92 cleared · 2008-2025

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

Device record: <https://www.510kdatabase.net/k081643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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