

K083412 PATHFAST HSCRIPMar 9, 2009
111 days to decisionK083412 · Product code: **DCN** · Chemistry
Source: <https://www.510kdatabase.net/k083412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Nov 18, 2008
Decision date	Mar 9, 2009
Days to decision	111 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mitsubishi Kagaku Iatron
Location	Seattle, WA, US
Contact	HELEN LANDICHO
510(k) history	4 submissions · 4 cleared · 2008-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026