

**K083080 IGX PLEX RHEUMATOID ARTHRITIS (RA) ASSAY AND
SQIDWORKS DIAGNOSTICS PLATFORM**Oct 29, 2009
378 days to decisionK083080 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k083080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Oct 16, 2008
Decision date	Oct 29, 2009
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sqi Diagnostics Systems
Location	Toronto, On, CA
Contact	Kate Smith
510(k) history	2 submissions · 2 cleared · 2009-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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