K083080 IGX PLEX RHEUMATOID ARTHRITIS (RA) ASSAY AND SQIDWORKS DIAGNOSTICS PLATFORM

CLEARED

Oct 29, 2009
378 days to decision

K083080 · 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