

K102673 RHEUMATOID FACTOR IMMUNOLOGICAL TEST SYSTEMSep 30, 2011
379 days to decisionK102673 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k102673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Sep 16, 2010
Decision date	Sep 30, 2011
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MARTIN M MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102673/> 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 May 14, 2026