FDA 510(k) Premarket Notification

K100499 ORGENTEC RHEUMATOID FACTOR EIA

CLEARED

Oct 27, 2010
247 days to decision

K100499 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k100499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Feb 22, 2010
Decision date	Oct 27, 2010
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orgentec Diagnostika GmbH**
Location	Minneapolis, MN, US
Contact	Gary Lehnus
510(k) history	3 submissions · 3 cleared · 2003-2010