FDA 510(k) Premarket Notification

CLEARED

K101911 IMMUKNOW-THE CYLEX IMMUNE CELLFUNCTION ASSAY

Oct 18, 2010
101 days to decision

K101911 · Product code: **NID** · Hematology
Source: https://www.510kdatabase.net/k101911/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Proliferation, In Vitro, T Lymphocyte (NID)
Date received	Jul 9, 2010
Decision date	Oct 18, 2010
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cylex, Inc.**
Location	Baldwin, MD, US
Contact	Judi Smith
510(k) history	2 submissions · 2 cleared · 2002-2010