

K110274 AUTODELFIA NEONATAL IRT KITJun 10, 2011
130 days to decisionK110274 · Product code: **JNO** · Chemistry
Source: <https://www.510kdatabase.net/k110274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N-benzoyl-L-arginine Ethyl Ester (u.v.), Trypsin (JNO)
Date received	Jan 31, 2011
Decision date	Jun 10, 2011
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wallac Oy, A Subsidiary of Perkinelmer, Inc.
Location	Waltham, MA, US
Contact	SUSAN K HAMANN
510(k) history	3 submissions · 3 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110274/> 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 June 7, 2026