

K102419 GSP NEONATAL IRT KIT (3306-001U)Dec 16, 2010
113 days to decisionK102419 · Product code: **JNO** · Chemistry
Source: <https://www.510kdatabase.net/k102419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N-benzoyl-L-arginine Ethyl Ester (u.v.), Trypsin (JNO)
Date received	Aug 25, 2010
Decision date	Dec 16, 2010
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wallac Oy, Subsidiary of Perkinelmer
Location	Waltham, MA, US
Contact	SUSAN K HAMANN
510(k) history	1 submissions · 1 cleared · 2010-2010

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