

K961984 PORPHOBILINOGEN (PBG)Dec 10, 1996
203 days to decisionK961984 · Product code: **JNF** · Chemistry
Source: <https://www.510kdatabase.net/k961984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ion-exchange Resin, Ehrlich's Reagent, Porphobilinogen (JNF)
Date received	May 21, 1996
Decision date	Dec 10, 1996
Days to decision	203 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trace America, Inc.
Location	Miami, FL, US
Contact	David Johnston
510(k) history	22 submissions · 22 cleared · 1988-2001

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