

K914419 AMNIOTEST(TM)Sep 1, 1993
699 days to decisionK914419 · Product code: **HIO** · Chemistry
Source: <https://www.510kdatabase.net/k914419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Oct 3, 1991
Decision date	Sep 1, 1993
Days to decision	699 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pro-Lab, Inc.
Location	Mchenry, IL, US
Contact	JOACHIM SPARKUHL
510(k) history	27 submissions · 26 cleared · 1984-1995

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