

K900021 PERCU-SET(TM)Mar 29, 1990
86 days to decisionK900021 · Product code: **HIO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k900021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Jan 2, 1990
Decision date	Mar 29, 1990
Days to decision	86 days
Third-party review	No

APPLICANT

Company	E-Z-Em, Inc.
Location	Mchenry, IL, US
Contact	JACK T BERGER
510(k) history	56 submissions · 56 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k900021/>, 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 May 18, 2026