FDA 510(k) Premarket Notification

K900021 PERCU-SET(TM)

CLEARED

Mar 29, 1990
86 days to decision

K900021 · Product code: **HIO** · Obstetrics & Gynecology
Source: 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