FDA 510(k) Premarket Notification

K921738 SONO-VU US(TM), MODIFICATION

CLEARED

Apr 27, 1992
89 days to decision

K921738 · Product code: **HIO** · Radiology
Source: https://www.510kdatabase.net/k921738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Jan 29, 1992
Decision date	Apr 27, 1992
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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