

**K921738 SONO-VU US(TM), MODIFICATION**

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k921738/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026