

K890463 ULTRASOUND PROCEDURE TRAY AMNICENTESIS TRAYApr 7, 1989
67 days to decisionK890463 · Product code: **HIO** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k890463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SD
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Jan 30, 1989
Decision date	Apr 7, 1989
Days to decision	67 days
Third-party review	No

APPLICANT

Company	Critical Specialties, Inc.
Location	West Chester, PA, US
Contact	ARTHUR K FERRELL
510(k) history	1 submissions · 0 cleared · 1989-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890463/> 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 June 30, 2026