FDA 510(k) Premarket Notification

K901643 ISOFLO(TM) AMNIOCENTESIS TRAY

CLEARED

Jul 25, 1990
107 days to decision

K901643 · Product code: **HIO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k901643/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Apr 9, 1990
Decision date	Jul 25, 1990
Days to decision	107 days
Third-party review	No

APPLICANT

Company	**Healthdyne Cardiovascular, Inc.**
Location	Costa Mesa, CA, US
Contact	BILL WELCH
510(k) history	5 submissions · 4 cleared · 1989-1990