FDA 510(k) Premarket Notification

K923612 MODIFIED F-10 CULTURE MEDIUM W/O HYPOXANTHINE

CLEARED

Sep 7, 1993
413 days to decision

K923612 · Product code: **MFD** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k923612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Intrauterine Insemination (MFD)
Date received	Jul 21, 1992
Decision date	Sep 7, 1993
Days to decision	413 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Life-Tech Intl., Inc.**
Location	Walker, MI, US
Contact	GARY J SFEIR
510(k) history	68 submissions · 66 cleared · 1982-2000