FDA 510(k) Premarket Notification

K922323 MX4042/MC4044 SERIES SIMULCATH(TM)

CLEARED

Jun 14, 1994
771 days to decision

K922323 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k922323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	May 4, 1992
Decision date	Jun 14, 1994
Days to decision	771 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medex, Inc.**
Location	Mchenry, IL, US
Contact	CATHY CHENETSKI
510(k) history	48 submissions · 46 cleared · 1977-2005