FDA 510(k) Premarket Notification

K950708 LIFETRACE INTRAUTERINE PRESSURE CATHETER IUP 3000

CLEARED

May 25, 1995
101 days to decision

K950708 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k950708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Feb 13, 1995
Decision date	May 25, 1995
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Graphic Controls Corp.**
Location	Mchenry, IL, US
Contact	IGNATY GUSAKOV
510(k) history	55 submissions · 55 cleared · 1977-1998