FDA 510(k) Premarket Notification

K895763 ISOFLO AND ISOTEC INTRAUTERINE PRESSURE MONITORING

CLEARED

Dec 22, 1989
87 days to decision

K895763 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k895763/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Sep 26, 1989
Decision date	Dec 22, 1989
Days to decision	87 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