FDA 510(k) Premarket Notification

K894362 MODEL DT-IUPC2 TRANSDUCER TIPPED DUAL LUMEN IUP

CLEARED

Aug 15, 1989
32 days to decision

K894362 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k894362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Jul 14, 1989
Decision date	Aug 15, 1989
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Spectramed, Inc.**
Location	Findley, MN, US
Contact	ROBERT L LEAVITT
510(k) history	13 submissions · 13 cleared · 1987-1990