FDA 510(k) Premarket Notification

K883334 BIODOP(TM)

CLEARED

Dec 15, 1988
128 days to decision

K883334 · Product code: **HEK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k883334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Heart Sound, Fetal, Ultrasonic (HEK)
Date received	Aug 9, 1988
Decision date	Dec 15, 1988
Days to decision	128 days
Third-party review	No

APPLICANT

Company	**Diagnosis Related Systems, Inc.**
Location	Hialeah, FL, US
Contact	VICTOR VALDES
510(k) history	1 submissions · 1 cleared · 1988-1988