FDA 510(k) Premarket Notification

K771211 DOPPLER (UTD-5 & UTD-6)

CLEARED

Jul 14, 1977
9 days to decision

K771211 · Product code: **HEK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k771211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Heart Sound, Fetal, Ultrasonic (HEK)
Date received	Jul 5, 1977
Decision date	Jul 14, 1977
Days to decision	9 days
Third-party review	No

APPLICANT

Company	**Terumo America, Inc.**
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1981