FDA 510(k) Premarket Notification

K802670 CONTIUOUS WAVE DOPPLER ULTRASOUND

CLEARED

Nov 26, 1980
30 days to decision

K802670 · Product code: **DXK** · Cardiovascular
Source: https://www.510kdatabase.net/k802670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Echocardiograph (DXK)
Date received	Oct 27, 1980
Decision date	Nov 26, 1980
Days to decision	30 days
Third-party review	No

APPLICANT

Company	**American Edwards Laboratories**
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987