FDA 510(k) Premarket Notification

K812209 ULTRA COM

CLEARED

Nov 16, 1981
104 days to decision

K812209 · Product code: **DXK** · Cardiovascular
Source: https://www.510kdatabase.net/k812209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Echocardiograph (DXK)
Date received	Aug 4, 1981
Decision date	Nov 16, 1981
Days to decision	104 days
Third-party review	No

APPLICANT

Company	**Ultranamics, Inc.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1981-1981