FDA 510(k) Premarket Notification

K812646 SKI 5000

CLEARED

Nov 16, 1981
60 days to decision

K812646 · Product code: **DXK** · Cardiovascular
Source: https://www.510kdatabase.net/k812646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Echocardiograph (DXK)
Date received	Sep 17, 1981
Decision date	Nov 16, 1981
Days to decision	60 days
Third-party review	No

APPLICANT

Company	**Smithkline Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	42 submissions · 42 cleared · 1976-1996