FDA 510(k) Premarket Notification

K781855 LVV OPTION

CLEARED

Jan 5, 1979
60 days to decision

K781855 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k781855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Nov 6, 1978
Decision date	Jan 5, 1979
Days to decision	60 days
Third-party review	No

APPLICANT

Company	**Honeywell, Inc.**
Location	Mchenry, IL, US
510(k) history	69 submissions · 69 cleared · 1976-1990

Honeywell, Inc. is an American multinational conglomerate headquartered in Charlotte, North Carolina. The company operates across aerospace, building automation, industrial automation, and energy solutions. Honeywell's medical device regulatory history spans from 1976 to 1990. The company received FDA 510(k) clearances from total submissions. Cardiovascular devices represented the dominant focus, accounting for approximately 75% of submissions. This historical record reflects the company's past involvement in patient monitoring systems, defibrillators, and related cardiov...