

K800553 ULTRA IMAGERJul 21, 1980
132 days to decisionK800553 · Product code: **DXK** · Cardiovascular
Source: <https://www.510kdatabase.net/k800553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Echocardiograph (DXK)
Date received	Mar 11, 1980
Decision date	Jul 21, 1980
Days to decision	132 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...

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