FDA 510(k) Premarket Notification

K802316 PDS THERMAL DILUTION CARDIAC MODULE(OUT)

CLEARED

Nov 26, 1980
64 days to decision

K802316 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k802316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Sep 23, 1980
Decision date	Nov 26, 1980
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**General Electric Co.**
Location	Mchenry, IL, US
510(k) history	254 submissions · 254 cleared · 1976-2011