FDA 510(k) Premarket Notification

K812515 CARDIAC REVIEW STATION

CLEARED

Oct 2, 1981
30 days to decision

K812515 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k812515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Sep 2, 1981
Decision date	Oct 2, 1981
Days to decision	30 days
Third-party review	No

APPLICANT

Company	**Diasonics, Inc.**
Location	Mchenry, IL, US
510(k) history	42 submissions · 41 cleared · 1978-1997