FDA 510(k) Premarket Notification

K790513 HLA-2000

CLEARED

May 31, 1979
77 days to decision

K790513 · Product code: **DRM** · Cardiovascular
Source: https://www.510kdatabase.net/k790513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Cardiac, External (DRM)
Date received	Mar 15, 1979
Decision date	May 31, 1979
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Bdt Ent.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1979-1979