FDA 510(k) Premarket Notification

K823345 PATCH

CLEARED

Mar 10, 1983
122 days to decision

K823345 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k823345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene (DXZ)
Date received	Nov 8, 1982
Decision date	Mar 10, 1983
Days to decision	122 days
Third-party review	No

APPLICANT

Company	**Shiley, Inc.**
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993