

K942010 VASCU-GUARDJul 7, 1994
73 days to decisionK942010 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k942010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Apr 25, 1994
Decision date	Jul 7, 1994
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Vascular, Inc.
Location	St. Paul, MN, US
Contact	BRUCE A MACFARLANE
510(k) history	26 submissions · 25 cleared · 1986-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 20, 2026