

K953289 TETRAFLUOROETHYLENE (TFE) POLYMER PLEDGETAug 21, 1995
38 days to decisionK953289 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k953289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Jul 14, 1995
Decision date	Aug 21, 1995
Days to decision	38 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Davis & Geck, Inc.
Location	Mchenry, IL, US
Contact	LYNNE A NEWQUIST
510(k) history	45 submissions · 42 cleared · 1981-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953289/> 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 22, 2026