

K982810 SHELHIGH NO-REACT VASCUPATCHOct 28, 1998
78 days to decisionK982810 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k982810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Aug 11, 1998
Decision date	Oct 28, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shelhigh, Inc.
Location	Union, NJ, US
Contact	SHLOMO GABBAY
510(k) history	8 submissions · 8 cleared · 1997-2003

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