

K974914 SHELHIGH NO-REACT PERICARDIAL PATCHESJun 3, 1998
177 days to decisionK974914 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k974914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Dec 8, 1997
Decision date	Jun 3, 1998
Days to decision	177 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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