

K964467 SHELHIGH PERICARDIAL PATCHSep 23, 1997
320 days to decisionK964467 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k964467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Nov 7, 1996
Decision date	Sep 23, 1997
Days to decision	320 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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