

**K151865 PremiPatch PTFE Pledget**Oct 27, 2015  
111 days to decisionK151865 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k151865/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Jul 8, 2015
Decision date	Oct 27, 2015
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aesculap, Inc.</b>
Location	Burlingame, CA, US
Contact	KATHY A. RACOSKY
510(k) history	207 submissions · 201 cleared · 1991-2025

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