

K812254 DACRON PLEDGET SUTURE BUTTRESSAug 31, 1981
19 days to decisionK812254 · Product code: **DXZ** · CardiovascularSource: <https://www.510kdatabase.net/k812254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Aug 12, 1981
Decision date	Aug 31, 1981
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Website	https://www.jnjmedtech.com
510(k) history	204 submissions · 197 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...
