FDA 510(k) Premarket Notification

K801660 PROXIMATE * PSD PURSE-STRING DEVICE

CLEARED

Aug 13, 1980
23 days to decision

K801660 · Product code: **GDJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k801660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Surgical, General & Plastic Surgery (GDJ)
Date received	Jul 21, 1980
Decision date	Aug 13, 1980
Days to decision	23 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...