FDA 510(k) Premarket Notification

K821178 ETHICON EXTERNAL FIXATION WIRE

CLEARED

Jun 11, 1983
410 days to decision

K821178 · Product code: **FYI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k821178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Facial Fracture, External (FYI)
Date received	Apr 27, 1982
Decision date	Jun 11, 1983
Days to decision	410 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...