

K946271 VICRYO* (POLYGLACTIN 910) BRAIDED COATED AND UNCOATED SYNTHETIC ABSORBABLE SUTURE, DYED & UNDYED, BRAIDED AND MONOFILAMT

Jun 15, 1995
174 days to decision

K946271 · Product code: **GAM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k946271/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Dec 23, 1994
Decision date	Jun 15, 1995
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	JOHN D PAULSON
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...