

K113004 PDS(TM) BARBED SUTURESDec 20, 2011
74 days to decisionK113004 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k113004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Oct 7, 2011
Decision date	Dec 20, 2011
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	PETER CECCHINI
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...
