FDA 510(k) Premarket Notification

CLEARED

K963783 MITEK ELECTROSURGICAL SYSTEM FOR ARTHROSCOPIC USE

Nov 25, 1996
66 days to decision

K963783 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k963783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 20, 1996
Decision date	Nov 25, 1996
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	EDWARD F KENT
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...