FDA 510(k) Premarket Notification

CLEARED

K061050 GYNECARE MORCELLEX TISSUE MORCELLATOR, MODELS MX0100 AND MX0100R

Jul 14, 2006
88 days to decision

K061050 · Product code: **HET** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k061050/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Apr 17, 2006
Decision date	Jul 14, 2006
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	BRYAN LISA
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...