FDA 510(k) Premarket Notification

K972072 SURGITRON MODEL FFPF-EMC

CLEARED

Jun 19, 1997
16 days to decision

K972072 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k972072/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 3, 1997
Decision date	Jun 19, 1997
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ellman Intl., Inc.**
Location	Hewlett, NY, US
Contact	FRANK LIN
510(k) history	15 submissions · 15 cleared · 1996-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972072/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026