FDA 510(k) Premarket Notification

K001407 SURGITRON IEC II

CLEARED

Jul 24, 2000
81 days to decision

K001407 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k001407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 4, 2000
Decision date	Jul 24, 2000
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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