FDA 510(k) Premarket Notification

CLEARED

K013255 SURGITRON 120 IEC (ALSO KNOWN AS SURGITRON 4.0 DUAL RF

Nov 7, 2001
40 days to decision

K013255 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013255/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 28, 2001
Decision date	Nov 7, 2001
Days to decision	40 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