FDA 510(k) Premarket Notification

K992382 SURGITRON RADIOLASE

CLEARED

Oct 14, 1999
90 days to decision

K992382 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k992382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 16, 1999
Decision date	Oct 14, 1999
Days to decision	90 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