FDA 510(k) Premarket Notification

K972299 BERGEN MODEL 500 ELECTROSURGERY GENERATOR

CLEARED

Aug 27, 1997
69 days to decision

K972299 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k972299/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 19, 1997
Decision date	Aug 27, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bergen Mfg.**
Location	New Port Richey, FL, US
Contact	ROGER OOSTEN
510(k) history	4 submissions · 4 cleared · 1986-1997