FDA 510(k) Premarket Notification

K964736 BERGEN 610 BIPOLAR COAGULATOR

CLEARED

Feb 27, 1997
94 days to decision

K964736 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k964736/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 25, 1996
Decision date	Feb 27, 1997
Days to decision	94 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