

K972161 BOVIE MODEL X15Jun 18, 1997
9 days to decisionK972161 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k972161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 9, 1997
Decision date	Jun 18, 1997
Days to decision	9 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Maxxim Medical
Location	Arlington, TX, US
Contact	MICHAEL A CLARK
510(k) history	26 submissions · 25 cleared · 1994-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026