FDA 510(k) Premarket Notification

K972161 BOVIE MODEL X15

CLEARED

Jun 18, 1997
9 days to decision

K972161 · Product code: **GEI** · General & Plastic Surgery
Source: 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