FDA 510(k) Premarket Notification

K971450 SOMNOPLASTY SYSTEM

CLEARED

Jul 17, 1997
87 days to decision

K971450 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k971450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 21, 1997
Decision date	Jul 17, 1997
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Somnus Medical Technologies, Inc.**
Location	Sunnyvale, CA, US
Contact	EVE CONNER
510(k) history	16 submissions · 16 cleared · 1996-2000