FDA 510(k) Premarket Notification

K982717 SOMNOPLASTY SYSTEM, MODELS S2, 1010/2010,2000/1000,1100,3000/30XX/6000, 1200

CLEARED

Nov 2, 1998
90 days to decision

K982717 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k982717/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 4, 1998
Decision date	Nov 2, 1998
Days to decision	90 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