FDA 510(k) Premarket Notification

K012631 REPROCESSED SOFT TISSUE ABLATORS

CLEARED

Dec 6, 2001
115 days to decision

K012631 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 13, 2001
Decision date	Dec 6, 2001
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alliance Medical Corp.**
Location	Phoenix, AZ, US
Contact	DON SELVEY
510(k) history	36 submissions · 36 cleared · 2001-2007