FDA 510(k) Premarket Notification

K013369 RESECTION ABLATOR

CLEARED

Apr 4, 2002
175 days to decision

K013369 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 11, 2001
Decision date	Apr 4, 2002
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Linvatec Corp.**
Location	Research Triangle Pa, NC, US
Contact	LAURA D SENEFF
510(k) history	93 submissions · 87 cleared · 1992-2009