FDA 510(k) Premarket Notification

K012700 VANGUARD REPROCESSED ENDOSCOPIC INSTRUMENTS

CLEARED

Nov 7, 2001
85 days to decision

K012700 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 14, 2001
Decision date	Nov 7, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vanguard Medical Concepts, Inc.**
Location	Plant City, FL, US
Contact	MIKE SAMMON
510(k) history	33 submissions · 33 cleared · 1991-2005