FDA 510(k) Premarket Notification

K971092 QA-ES

CLEARED

Apr 23, 1997
28 days to decision

K971092 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k971092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 26, 1997
Decision date	Apr 23, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Smith**
Location	Crofton, MD, US
Contact	E.J. Smith
Website	http://www.si.edu/
510(k) history	5 submissions · 5 cleared · 1997-1998