FDA 510(k) Premarket Notification

K012362 MODIFICATION TO VASCULAR CLOSURE DEVICE

CLEARED

Aug 23, 2001
29 days to decision

K012362 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Staple, Implantable (GDW)
Date received	Jul 25, 2001
Decision date	Aug 23, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Std Mfg., Inc.**
Location	Stoughton, MA, US
Contact	STEPHEN M PALUMBO
510(k) history	6 submissions · 6 cleared · 1993-2003