FDA 510(k) Premarket Notification

K050150 MANI NEEDLE & SUTURE PACK

CLEARED

Dec 5, 2005
315 days to decision

K050150 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k050150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Jan 24, 2005
Decision date	Dec 5, 2005
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mani, Inc.**
Location	Washington, DC, US
Contact	DAVID J BLOCH
510(k) history	4 submissions · 4 cleared · 2005-2006