

**K050150 MANI NEEDLE & SUTURE PACK**Dec 5, 2005  
315 days to decisionK050150 · Product code: **GAT** · General & Plastic SurgerySource: <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	<b>Mani, Inc.</b>
Location	Washington, DC, US
Contact	DAVID J BLOCH
510(k) history	4 submissions · 4 cleared · 2005-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050150/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026