

**K192088 GOLNIT Non-aborbable PTFE Surgical Suture**Sep 4, 2019  
30 days to decisionK192088 · Product code: **NBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192088/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene (NBY)
Date received	Aug 5, 2019
Decision date	Sep 4, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Antarma, LLC Db a Golnit Sutures</b>
Location	New York, NY, US
Contact	Armine Badalyan
510(k) history	2 submissions · 2 cleared · 2019-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192088/> 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 7, 2026