

**K180992 Biotex**Jul 16, 2019  
456 days to decisionK180992 · Product code: **NBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180992/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene (NBY)
Date received	Apr 16, 2018
Decision date	Jul 16, 2019
Days to decision	456 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Purgo Biologics, Inc.</b>
Location	Seongnam-Si, KR
Contact	Seonghwan Song
510(k) history	6 submissions · 6 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180992/> 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 May 26, 2026