

**K991191 BONDEK POLYGLYCOLIC ACID SYNTHETIC  
ABSORBABLE SURGICAL SUTURE**Jun 22, 1999  
75 days to decisionK991191 · Product code: **GAM** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k991191/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Apr 8, 1999
Decision date	Jun 22, 1999
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Genzyme Surgical Product (Genzyme Biosurgery)</b>
Location	Fall River, MA, US
Contact	MARY E GRAY
510(k) history	9 submissions · 8 cleared · 1998-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991191/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026