

**K021019 COTTONY II, SILKY II POLYDEK & TEVDEK II  
POLYESTER SUTURE**Jun 18, 2002  
81 days to decisionK021019 · Product code: **GAT** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k021019/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Suture, Nonabsorbable, Synthetic, Polyethylene (GAT) |
| Date received         | Mar 29, 2002   |
| Decision date         | Jun 18, 2002   |
| Days to decision      | 81 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Genzyme Corp.</b>  |
| Location       | Cambridge, MA, US   |
| Contact        | MARY GRAY   |
| Website        | <a href="http://www.genzyme.com">http://www.genzyme.com</a> |
| 510(k) history | 27 submissions · 27 cleared · 1991-2006                     |

Genzyme Corp. was an American biotechnology company headquartered in Cambridge, Massachusetts. The company specialized in diagnostic and surgical medical devices across multiple therapeutic areas. Genzyme received FDA 510(k) clearances from total submissions between 1991 and 2006. The company's cleared devices spanned chemistry devices, microbiology diagnostics, and surgical implants including wound closure systems and bioresorbable barriers. This regulatory track record reflects the company's broad portfolio across diagnostic and surgical specialties. Genzyme was acquire...