

**K001434 &apos;COTTONY&apos;; II DACRON, SILKY II  
POLYDEK & TEVDEK II POLYESTER NONABSORBABLE  
SURGICAL SUTURE**Jun 12, 2000  
35 days to decisionK001434 · Product code: **GAT** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k001434/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	May 8, 2000
Decision date	Jun 12, 2000
Days to decision	35 days
Third-party review	No

**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/k001434/> Data sourced from FDA 510(k) public records (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 25, 2026