

K001440 NEXTSTITCH CARDIOVASCULAR VALVE SUTURENov 13, 2000
189 days to decisionK001440 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k001440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	May 8, 2000
Decision date	Nov 13, 2000
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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