

K030212 MONODEK SYNTHETIC ABSORBABLE SURGICAL SUTUREMar 27, 2003
65 days to decisionK030212 · Product code: **NEW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k030212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Jan 21, 2003
Decision date	Mar 27, 2003
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Biosurgery
Location	Fall River, MA, US
Contact	STEVE PAGE
510(k) history	4 submissions · 4 cleared · 2002-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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