

**K093112 DIGITEX SUTURE DELIVERY SYSTEM, MODEL 52025,
DIGITEX SUTURE CARTRIDGE (SIZE O), MODEL 52026,
DIGITEX SUTURE CARTRIDGE**Feb 1, 2010
123 days to decisionK093112 · Product code: **GAW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k093112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	Oct 1, 2009
Decision date	Feb 1, 2010
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Manufacturing Us, LLC
Location	Minneapolis, MN, US
Contact	JANELL COLLEY
510(k) history	4 submissions · 4 cleared · 2007-2010

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