

**K163098 Tri-Staple 2.0 Intelligent Cartridge**Dec 5, 2016  
28 days to decisionK163098 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Staple, Implantable (GDW)
Date received	Nov 7, 2016
Decision date	Dec 5, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	REBECCA BREWER
510(k) history	88 submissions · 85 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163098/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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 June 2, 2026