

**K221487 NEOVEIL Staple Line Reinforcement**Aug 26, 2022  
95 days to decisionK221487 · Product code: **OXC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221487/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Absorbable, Staple Line Reinforcement (OXC)
Date received	May 23, 2022
Decision date	Aug 26, 2022
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gunze Limited</b>
Location	Ayabe, Kyoto, JP
Contact	Hidenori Nishioka
510(k) history	5 submissions · 5 cleared · 2013-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Stuart R. Goldman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221487/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026