

K231603 Standard Staple-Line Reinforcement (SSLR23)Oct 6, 2023
127 days to decisionK231603 · Product code: **OXC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Staple Line Reinforcement (OXC)
Date received	Jun 1, 2023
Decision date	Oct 6, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Standard Bariatrics, Inc.
Location	Cincinnati, OH, US
Contact	Trevor Barton
510(k) history	2 submissions · 2 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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