

**K201153 Tisuthes e-PTFE Surgical Patch**

Jun 13, 2023

1139 days to decision

K201153 · Product code: **OWR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-absorbable, Facial Implants For Plastic Surgery (OWR)
Date received	Apr 30, 2020
Decision date	Jun 13, 2023
Days to decision	1139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Suokang Medical Implants Co., Ltd.</b>
Location	Shanghai, CN
Contact	Lixinhua Lixinhua
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201153/> 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 27, 2026