

**K942280 GORETEX SAM FACIAL IMPLANT**Jul 28, 1994  
79 days to decisionK942280 · Product code: **FWP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k942280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Chin, Internal (FWP)
Date received	May 10, 1994
Decision date	Jul 28, 1994
Days to decision	79 days
Third-party review	No

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	JOHN W NICHOLSON
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...

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