

**K961210 SAM FACIAL IMPLANT**Jun 19, 1996  
83 days to decisionK961210 · Product code: **LZK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k961210/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Malar (LZK)
Date received	Mar 28, 1996
Decision date	Jun 19, 1996
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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...

---