

**K971916 MEDICAL Z, S.A. MEDIGEL Z SCAR MANAGEMENT GEL**Jul 29, 1997  
67 days to decisionK971916 · Product code: **MDA** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k971916/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	May 23, 1997
Decision date	Jul 29, 1997
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medical Z, S.A.</b>
Location	Washington, DC, US
Contact	EMALEE G MURPHY
510(k) history	1 submissions · 1 cleared · 1997-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971916/> Data sourced from FDA 510(k) public records (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. - Generated July 4, 2026