

K083718 BEAU RX SCAR CARE GELJan 26, 2009
42 days to decisionK083718 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Dec 15, 2008
Decision date	Jan 26, 2009
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beau RX Solutions, LLC
Location	Melbourne Beach, FL, US
Contact	THOMAS L MCGRAW
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083718/> 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 June 23, 2026