

K190443 MMSphereJun 24, 2019
119 days to decisionK190443 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Feb 25, 2019
Decision date	Jun 24, 2019
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Galactic Beauty, LLC
Location	New York, NY, US
Contact	Ellen Marmur
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190443/> 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 28, 2026