

K230100 SCIZER (SC1-M410)Nov 3, 2023
294 days to decisionK230100 · Product code: **OHV** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k230100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Jan 13, 2023
Decision date	Nov 3, 2023
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Classys, Inc.
Location	Seoul, KR
Contact	Elin Hong
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Elexes Medical Consulting, LLC
Contact	Parul Chansoria

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230100/> 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 May 26, 2026