

**K142833 INTRAGen**Jun 4, 2015  
247 days to decisionK142833 · Product code: **OUH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142833/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Skin Resurfacing Rf Applicator (OUH)
Date received	Sep 30, 2014
Decision date	Jun 4, 2015
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jeisys Medical, Inc.</b>
Location	Littleton, CO, US
Contact	Kyung Won Hwang
510(k) history	15 submissions · 15 cleared · 2008-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142833/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026