

**K150409 VIVACE Electrosurgical System**Jan 15, 2016  
331 days to decisionK150409 · Product code: **OUH** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k150409/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Skin Resurfacing Rf Applicator (OUH)
Date received	Feb 18, 2015
Decision date	Jan 15, 2016
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sung Hwan E&amp;B Co.,Ltd</b>
Location	Seongdong-Gu, KR
Contact	Sun Young Kang
510(k) history	1 submissions · 1 cleared · 2016-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150409/> 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 June 3, 2026