

**K213285 easy Claire**Mar 3, 2022  
153 days to decisionK213285 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213285/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Oct 1, 2021
Decision date	Mar 3, 2022
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Y &amp; J Bio Co., Ltd.</b>
Location	Seoul, KR
Contact	Chun Young Sam
510(k) history	5 submissions · 5 cleared · 2018-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mdr Solutions Co., Ltd.</b>
Contact	Paweena U-Thainual

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213285/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026