

K201107 Opera Lebody (Gold), Opera Lebody (Zafiro)Jun 22, 2020
59 days to decisionK201107 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k201107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Apr 24, 2020
Decision date	Jun 22, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gtg Wellness Co., Ltd.
Location	Yongin-Si, KR
Contact	Sang Won Jun
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Mdr Solutions Co., Ltd.
Contact	Paweena U-Thainual

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201107/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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