FDA 510(k) Premarket Notification

# K221989 The Oligio

**CLEARED**

Oct 13, 2022
99 days to decision

K221989 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221989/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jul 6, 2022 |
| Decision date | Oct 13, 2022 |
| Days to decision | 99 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Wontech Co., Ltd.** |
| Location | Daejeon, KR |
| Contact | Hyun Sik Yoon |
| 510(k) history | 28 submissions · 28 cleared · 2017-2025 |