FDA 510(k) Premarket Notification

# K211562 Virtue RF

**CLEARED**

Nov 23, 2021
187 days to decision

K211562 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211562/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | May 20, 2021 |
| Decision date | Nov 23, 2021 |
| Days to decision | 187 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **ShenB Co., Ltd.** |
| Location | Seongdong-Gu, KR |
| Contact | Sunny Kang |
| 510(k) history | 11 submissions · 11 cleared · 2020-2026 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Hoy and Associates** |
| Contact | Connie Hoy |

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