

**K250165 Pastelle**Jul 3, 2025  
163 days to decisionK250165 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250165/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Jan 21, 2025                            |
| Decision date         | Jul 3, 2025                             |
| Days to decision      | 163 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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