

**K120460 SMARTLUX**Oct 1, 2012  
229 days to decisionK120460 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k120460/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Feb 15, 2012                            |
| Decision date         | Oct 1, 2012                             |
| Days to decision      | 229 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Medmix Co., Ltd.</b>               |
| Location       | Pittsburgh, PA, US                    |
| Contact        | PETER CHUNG                           |
| 510(k) history | 2 submissions · 2 cleared · 2012-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120460/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026