

**K221083 Smartlux Mini**Jul 12, 2022  
90 days to decisionK221083 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221083/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 13, 2022
Decision date	Jul 12, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gms Consulting</b>
Contact	JongHyun Kim

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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